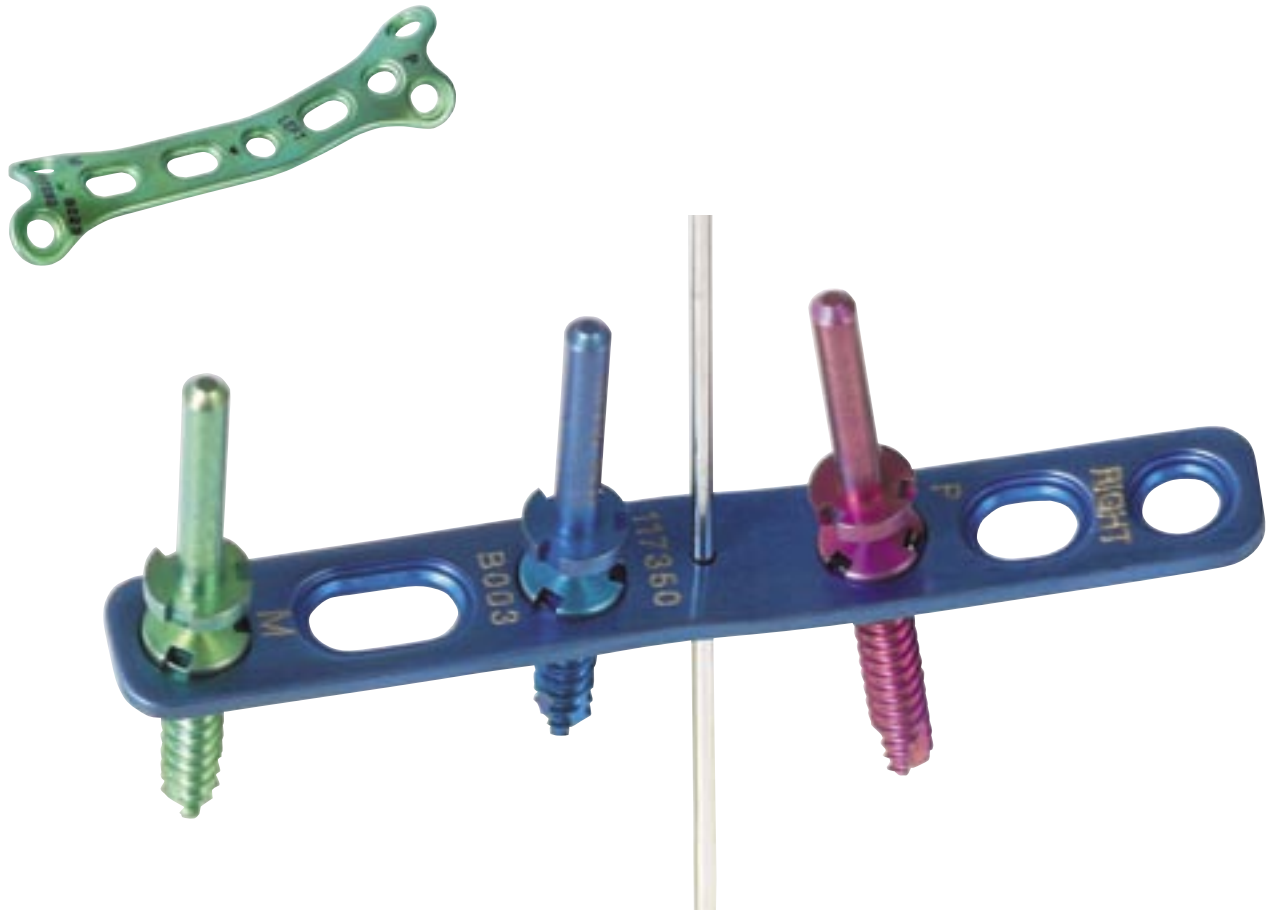
HALLU®-FIX

SURGICAL TECHNIQUE



M.T.P. arthrodesis Hallu®-Fix system

FOREFOOT SOLUTIONS™

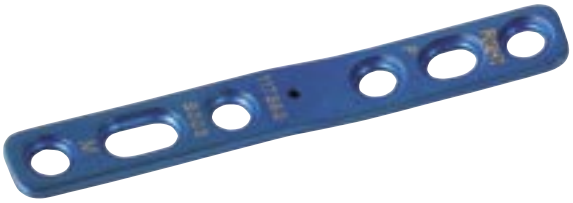
INTEGRA™

newdeal®
An Integra LifeSciences Company

HALLU®-FIX

The first COMPREHENSIVE system for MTP arthrodesis providing:

ANATOMICAL ADAPTATION ACCURACY VERSATILITY REPRODUCTIBILITY



Hallu®-C plate
MTP arthrodesis plate

Hallu®-S plate
Revision of MTP arthrodesis plate

Hallu® Snap-off
Snap-off screw

Hallu®-Ream
Phalangeal reamers

Hallu®-Ream
Metatarsal reamers

INDICATIONS

- Hallux rigidus
- Severe hallux valgus (Im angle>20° &HV angle> 40°)
- Deformity from rheumatoid arthritis
- Post traumatic arthritis
- Neuromuscular instability

Hallu®-S plate (only) : revision of Keller procedure, failed arthroplasty, failed fusion.

CONTRAINDICATIONS

- Limited skin coverage
- Severe osteoporosis
- Infection

SURGICAL TECHNIQUE

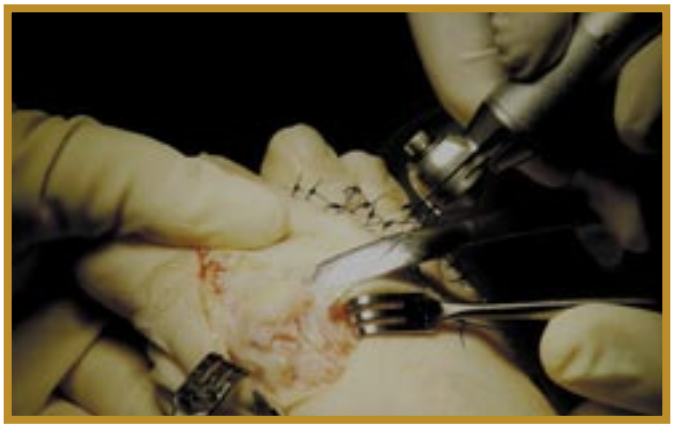
The foot is washed, prepped and draped in the normal sterile fashion.
The surgery is done under tourniquet to avoid bleeding.

I • INCISION

A dorsal longitudinal incision is commonly used. This enables correct exposure of the metatarso-phalangeal joint. The incision is centered just medial to the extensor hallucis longus, and deepened to the joint capsule, through the subcutaneous tissues. The joint capsule is released and retractors are placed to expose the base of the proximal phalanx and metatarsal head.

II • PREPARATION OF THE JOINT SURFACES WITH THE HALLU®-REAM SYSTEM

The amount of the bone resection depends upon the desired length of the 1st metatarsal. (Note: some revision cases will not require extensive resection). A power saw may be used to resect the base of the proximal phalanx and the articular surface of the 1st metatarsal head. A cut, resecting a small wafer of bone, perpendicular to the axis of the proximal phalanx is made just distal to the articular surface. A similar cut is made in the metatarsal head perpendicular to the long axis of the metatarsal shaft.

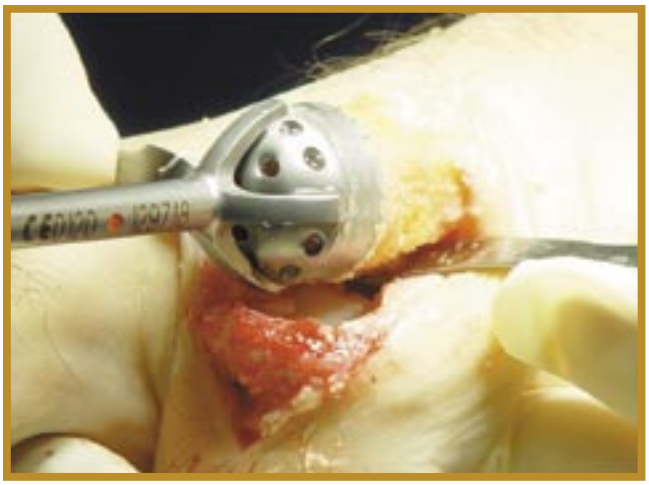


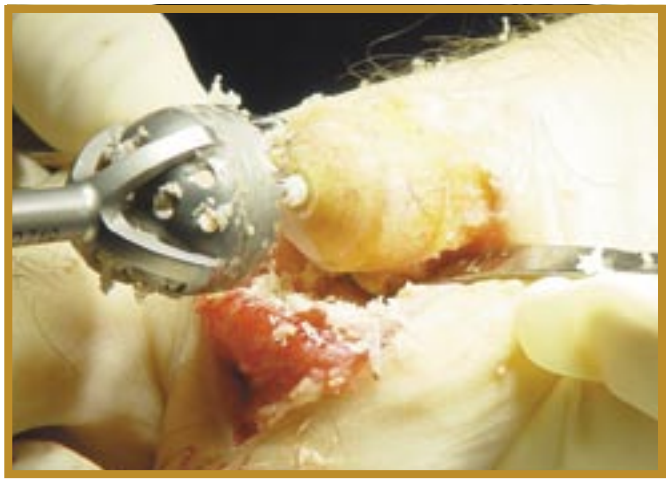
These cuts are made in order to decompress the joint, allowing the use of the reamers. Osteophytes should be carefully removed. Medial exostosis of the 1st metatarsal bone may also be resected.

Metatarsal preparation

The phalanx is plantar flexed to gain access to the metatarsal head. A 1.6 mm K-wire (ref: 115 216ND) is then introduced into the center of the metatarsal head and driven in a proximal direction along the axis of the diaphysis. The appropriate size of cannulated metatarsal reamer is selected by placing a reamer in front of the articular surface of the metatarsal head. If sizing is doubtful, it is advisable to begin by using the largest size reamer, and then downsizing to match the diameter of the metatarsal head.

Using the Quick coupling device (ref: 129 710ND) the Hallu®-ream reamer is then engaged over the 1.6 mm K-wire, and the metatarsal head is reamed. The 2 in 1 metatarsal reamer is bell shaped to allow barrel reaming and articular preparation in one step.

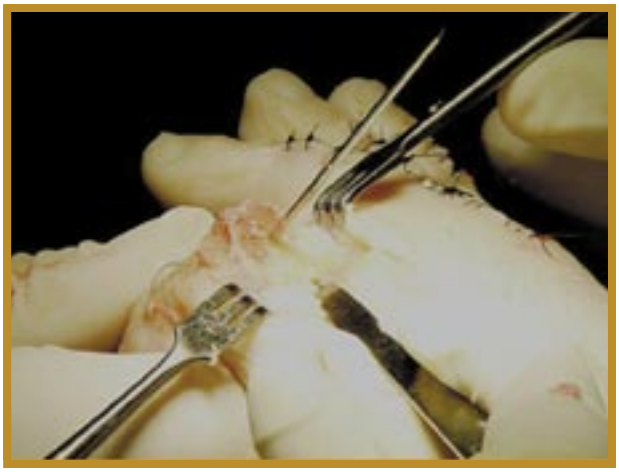




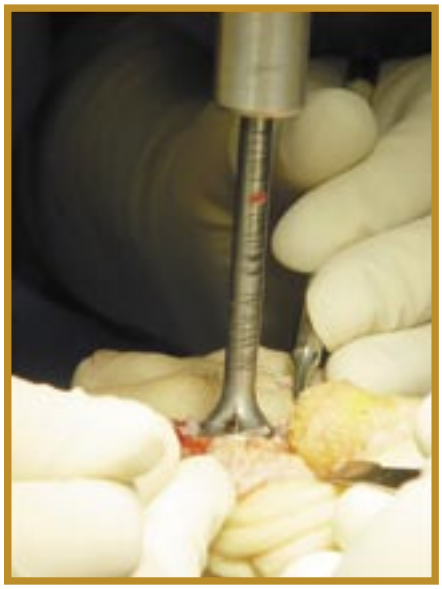
The metatarsal metaphysis is reduced to a cylinder of constant diameter, while the metatarsal head surface is reamed to a convex cup-shaped surface. The metatarsal reamer is removed. The K-wire can be held to elevate the metatarsal head to enable the removal of the bone on the plantar aspect. Excess bone is removed with an osteotome or a rongeur. Debris and bone fragments are cleaned and irrigated.

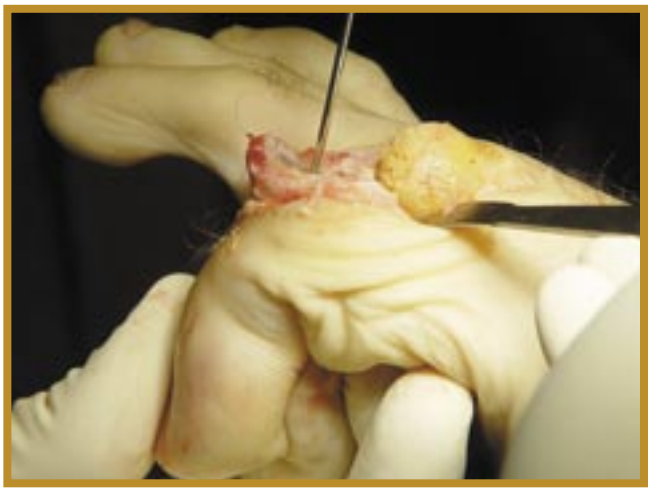
Phalangeal preparation

The proximal phalanx is plantar flexed. A Hohman retractor usually helps to expose the phalanx. A 1.6 mm K-wire (ref: 115 216ND) is placed in the center of the prepared base of the proximal phalanx and driven in a distal direction along the axis of the hallux.



Care is taken not to penetrate the interphalangeal joint. Reaming must begin by using the smallest size of phalangeal reamer, size 14 mm; in order to avoid any excessive reaming. The metatarsal head should be protected when reaming. The reamer is placed on the 1.6 mm K-wire, and the surface of the phalanx is reamed, creating a concave cup-shaped surface.





If necessary, due to the diameter of the articular surface of the phalanx, superior sizes of the phalangeal reamers can be used until the dimensions match the size used for the metatarsal reamer. When an additional bone graft is required, bone debris in the reamer can be used after the reaming process is complete.

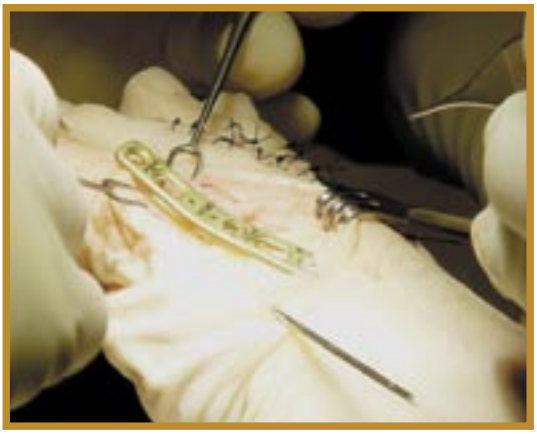
Warning:
The same size metatarsal and phalangeal reamers must be used to obtain congruent surfaces. (Example: if metatarsal reaming has been achieved with a 18 mm reamer, the largest and last reamer to be used for the phalanx should also be an 18 mm).

The reamer and K-wire are then removed. The cup shaped surfaces can be aligned in any desired position. It is then possible to rotate the surfaces, change the dorsi flexion, plantar flexion and valgus angles. A temporary K-wire is introduced from the phalanx to the metatarsal to stabilize the joint in the adequate position for final arthrodesis. Bone graft can then be placed into the joint.

III • HALLU®-FIX PLATE FIXATION

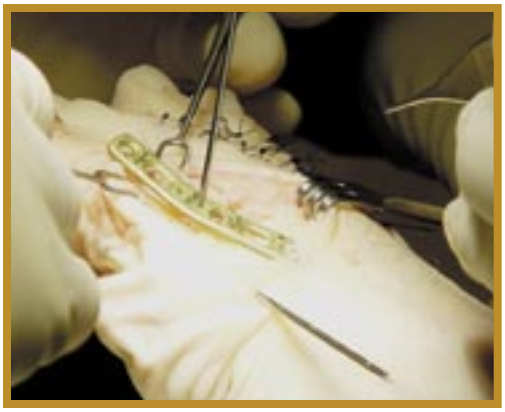
The selection of the appropriate size of the Hallu®-C or Hallu®-S plate (4, 5 or 6 holes) is done by positioning a plate on the dorsal aspect of the bone surfaces and assessing its dimensions. The plate has 2 marks on its dorsal aspect: P stands for Phalanx and M stands for Metatarsal. This orientation is mandatory.

The small central hole should be positioned over the center of the metatarsal head. In case of Revision (Hallu®-S plate), the positioning hole is used as "landmark" to create the center of the joint.



The Hallu®-Fix plates both have a 10° lateral angulation (10° valgus) as well as a 10° dorsal flexion. The Hallu®-C plate can be bent by using 2 benders (ref: 129 731ND & 129 732ND), right & left, to match the degree of dorsal flexion required by the case or by the activity of the patient

WARNING :
- **Do not bend the Hallu®-S plate.**
- **The plates should not be bent and rebent again.**

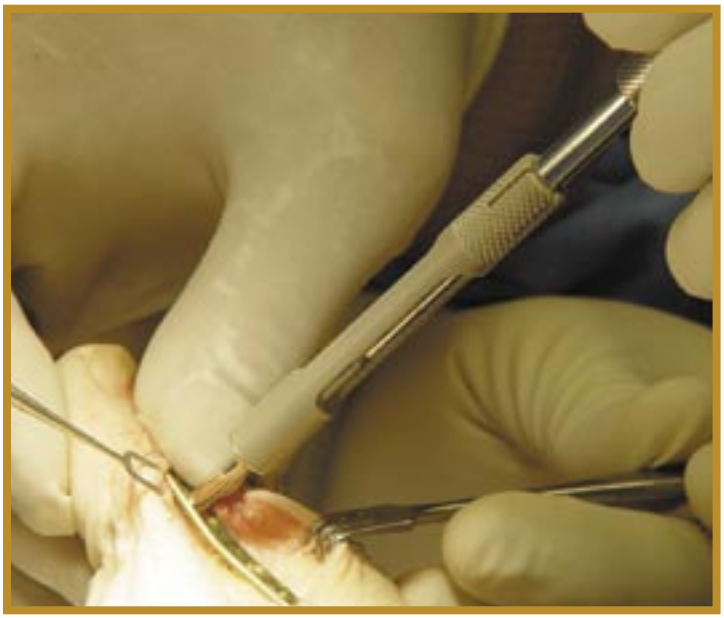


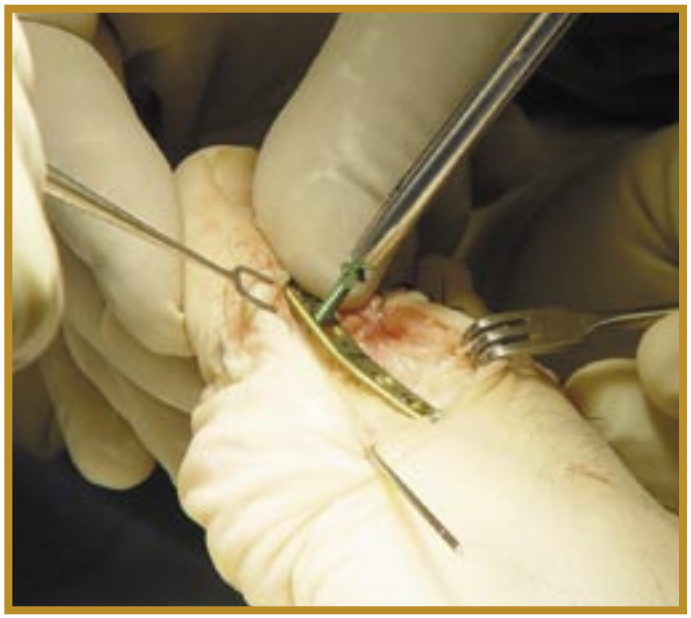
Once the correct size and type of plate has been chosen, and adequate alignment achieved, a 1 mm K-wire is inserted through the central hole of the plate in the metatarsal head for temporary stabilization.

The K-wire allows for rotation of the plate in order to obtain the ideal position.

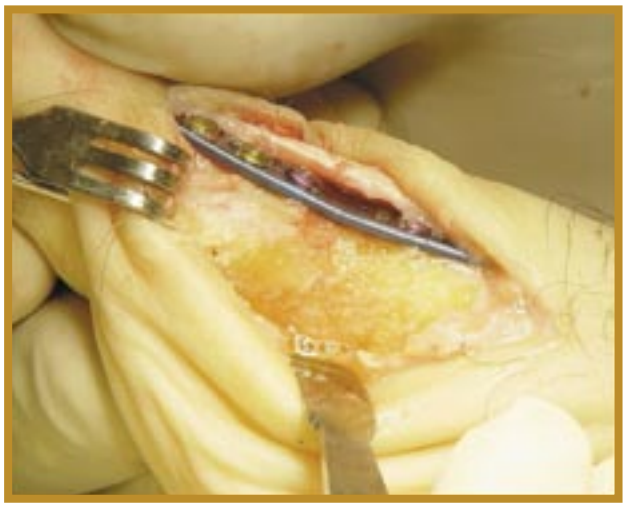
The 1.9 mm drill (ref: 119 618ND), with the drill guide (ref: 129 734ND), is used to prepare the holes in the dorsal cortex of the bone through the holes of the plate. The depth gauge (ref: 129 736ND) measures the adequate length of the screw. Two types of screws are available: standard 2.7 mm (length 12 to 28 mm) or fat boys 3.0 mm (length 12 to 18 mm). Bone quality will dictate the screw diameter to be used. Screws are color coded for easy identification

The selected snap-off screw is engaged into the cannulated screwdriver (ref: 129 733ND) or into a power instrument. When the head of the screw comes in contact with the plate, the barrel of the screw automatically snaps off.

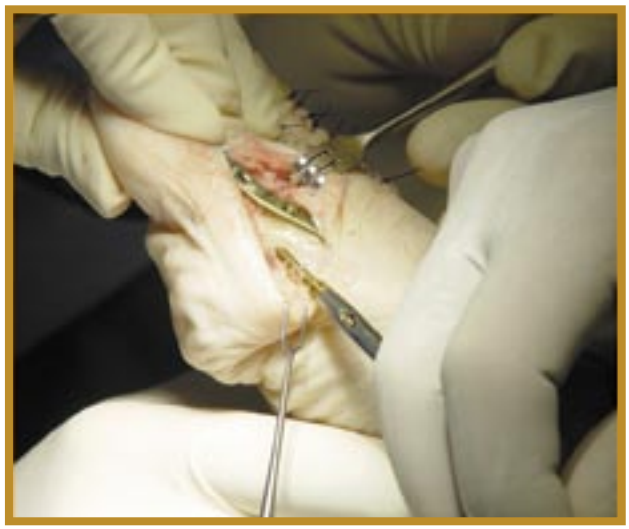




The screw can be tightened down with the screwdriver from the Hallu®-Fix system. The oblong holes allow for angled and compressive screw fixation. The central K-wire can be removed when solid fixation of the plate is achieved. When all the screws have been inserted on the plate, they are tightened along the dorsal aspect of the plate.

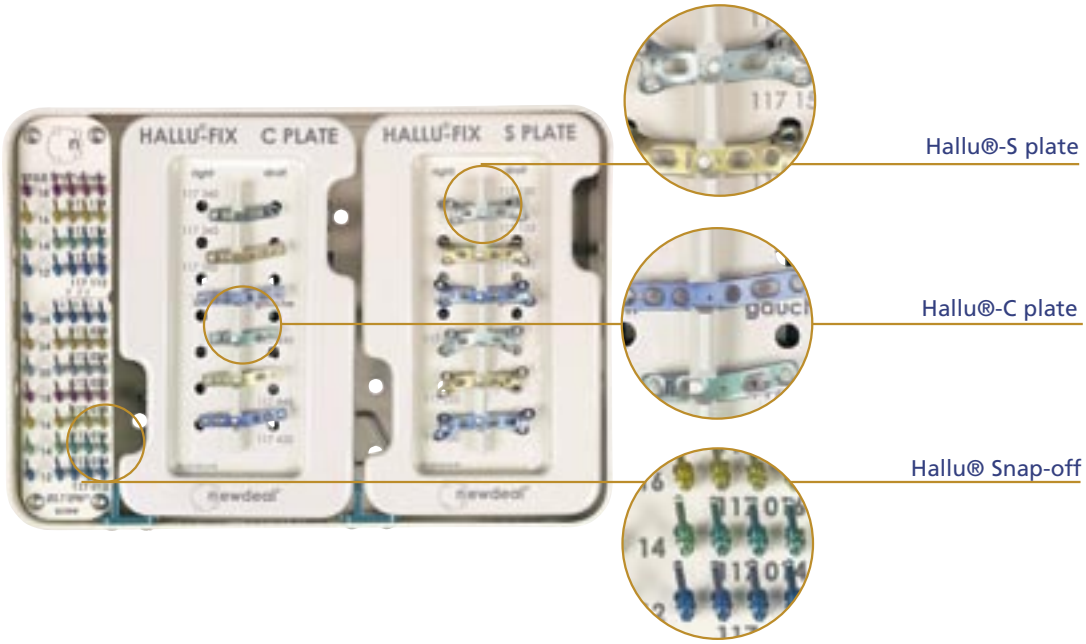


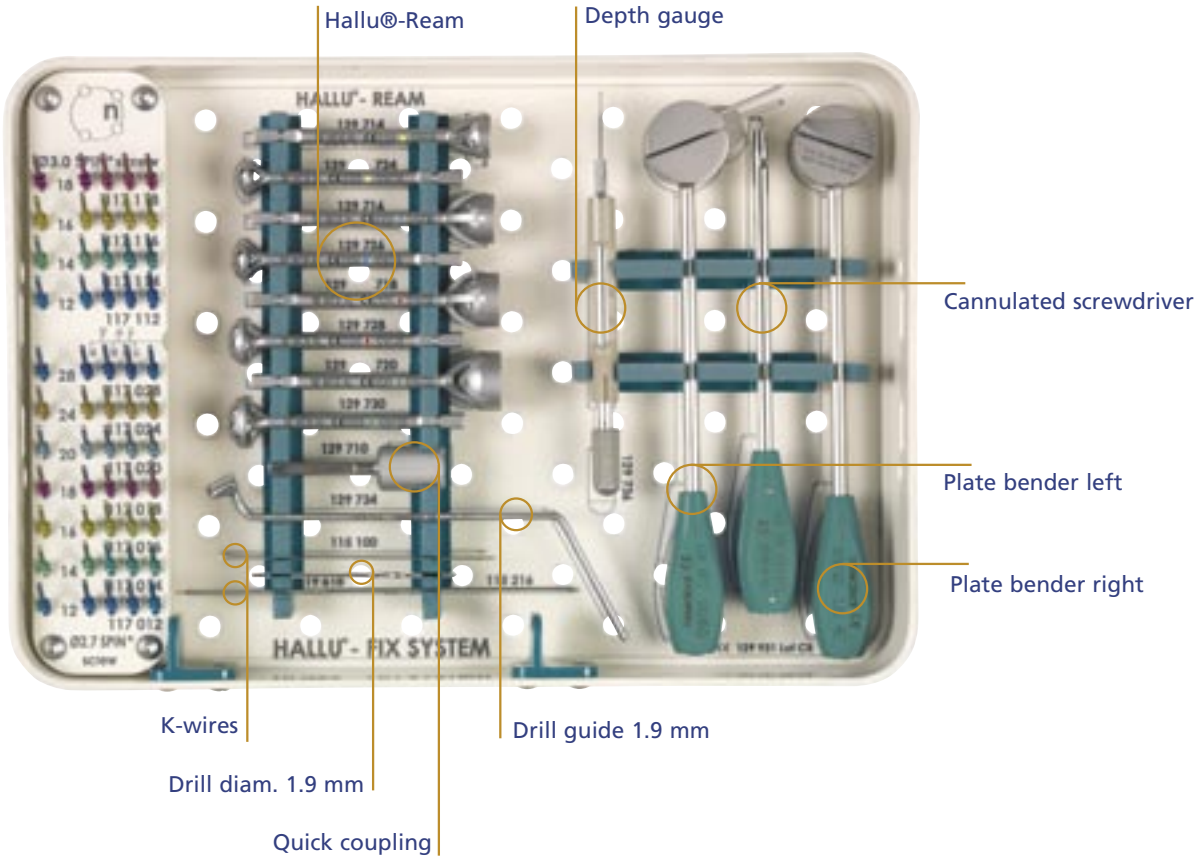
Note: a final additional screw can be directed across the plantar aspect of the joint.



Closure is then performed in the normal and routine fashion.

HALLU®-FIX ARTHRODESIS SET





HALLU®-FIX ARTHRODESIS SET
INSTRUCTIONS FOR USE
HALLU®-PLATES

NON-STERILE IMPLANTS FOR SURGERY • SINGLE USE

In accordance with EEC directive 93/42 relative to medical devices, this product must be handled and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1 - Description of the medical devices:
The implants - **delivered non-sterile** - are:
- **Osteosynthesis plates**, existing in different models and sizes
- They are made out of Titanium alloy within the frame of the standard ISO 5832-3 and ASTM F136

2 - Indications :
Depending on the model, the osteosynthesis plates are indicated for use in fixation of:
- Fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint (HALLU-FIX system, S-Plate and C-Plate), including cases of:
- Hallux rigidus
- Severe hallux valgus (IM angle > 20° and HV angle > 40°)
- Deformity from rheumatoid arthritis
- Failed previous surgical procedure
- Traumatic arthritis
- Neuromuscular instability.

3 - Contraindications:
The implant should not be used in a patient who has currently, or who has a history of:
- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- suspected or documented metal allergy or intolerance;

4 - Warnings:
Serious post-operative complications may occur from use of the implant in a patient who:
- Lacks good general physical condition;
- Has severe osteoporosis;
- Demonstrates physiologic or anatomic anomalies;
- Has immunological responses, sensitization, or hypersensitivity to foreign materials;
- Systemic or metabolic disorders;

5 - Precautions for use:
Physician must determine if implant is appropriate for patients who have any of the following conditions:
- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Infectious disease;
- Malignancy;
- Local bone tumors;
- Systemic or metabolic disorders or replacement;
- Compromised wound healing;
- Obesity;
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation;

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.
Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.
The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.
Complications with the use of osteosynthesis plates have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.
Possible risks, adverse reactions, and complications associated with surgery and the use of the osteosynthesis plates should be discussed with and understood by the patient prior to surgery. The implant is composed of titanium alloy materials; therefore, it is subject to possible reactions and complications, including those listed herein. The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide. The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.
IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.
Complications may include but are not limited to:
– Pain, discomfort, or abnormal sensations due to presence of the implant;
– Bending, loosening, and/or breakage, which could make removal impracticable or difficult;
– Risk of additional injury from post-operative trauma;
– Migration of the implant position or implant material resulting in injury;
– Bone loss due to stress shielding;
Side effects may include but are not limited to:
– Infections;
– Hematoma;
– Allergy;
– Thrombosis;
– Bone non union or delayed union.
Adverse effects may necessitate re-operation, revision or removal surgery , arthrodesis of the involved joint, and /or amputation of the limb.
Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
Interference risks during medical imaging:
MRI/SCANNER : ask the patient to systematically mention that he/she has undergone a surgical intervention at the foot level.

6 - Instructions for reprocessing:
This product is sold non-sterile.
Check the integrity of the packaging and labeling before opening the packing.
Remove all the products from their packaging prior to sterilization
All products should be cleaned, decontaminated, and sterilized before use.
Always immediately clean and decontaminate all devices that have been soiled.
Repeated reprocessing has little effect on these products.
Preparation: Double instruments (ex. Internal screwdriver and associated external screwdriver) should be separated prior to cleaning.
Cleaning: Cleaning can be performed manually, automatically or ultrasonically in accordance with the specifications designated by the manufacturer of the hospital's equipment.
Manual cleaning: Manual cleaning consists of using aldehyde free cleaners (neutral or alkaline), applied with a soft brush, taking special care to threaded parts and parts difficult to reach.
Note: Certain solutions such as those containing bleach or formalin may damage the devices, and they must not be used. Use of metallic brushes or other abrasive products is also forbidden.
Cleaning should be immediately followed by profusely rinsing with deionized water. Check that water flows out the cannulated parts.
Automatic cleaning: Automatic cleaning is performed in a cleaning/disinfecting machine using neutral cleaners, with a cleaning cycle of 5 minutes minimum and a rinsing cycle of 3 minutes.
Check the complete removal of visible dirt, especially in the cannulated parts.
If necessary, repeat the full process or proceed to a manual cleaning.
Disinfection: If an automatic cleaning is used, final rinsing at 80°C during 10 minutes can be performed.
Drying: Drying temperature should not exceed 80°C.
Controls, servicing and tests : No specific requirements.
The implants are single use. They should therefore never be re-used.
Packaging: No specific requirements.
Sterilization: Newdeal's implants and instruments are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital.
The following two methods have been validated by the manufacturer and can thus be used:

Method: steam Cycle: wrapped gravity temperature: 132°C Exposure time: 45 minutes	Method: steam Cycle: wrapped gravity temperature: 134°C Exposure time: 18 minutes

Other sterilization method and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques.
EtO sterilization or cold sterilization techniques are not recommended.

7 - Use of the implant:
The surgeon must use the instrumentations recommended in accordance with the operative technique available from the manufacturer. The medical device must be used in compliance with the use of the profession and the standard of art. Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.
Opening of the instruments set must be done according to aseptic condition.
When handling the implants, avoid any contact with other material or tools which may damage the implant surface. Under no circumstances should the implant be modified .

8 - Re-use of the implants:
Orthopedic implants already implanted must never be re-used. The company accepts no responsibility for such re-use.

9 - Re-sterilization of non implanted products:
Re-sterilization is only allowed for non implanted products.
The implants can be sterilized several times in the same conditions as those described in paragraph 6.

10 - Preventative actions for the patient to avoid post-operative complications:
- Avoid extreme position such as flexion-extension
- Wear orthopedic shoes according to the surgeon's prescription
- Receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

11 - Storage: Store in dry place

12 - Liability:
Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Newdeal neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Newdeal intends that this device should be used only by physicians having received appropriate training in orthopedic surgery techniques.

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

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION:
Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

HALLU®-FIX ARTHRODESIS SET
INSTRUCTIONS FOR USE
HALLU®-SNAP-OFF

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2 - Indications:
They are indicated for use in: **fixation of arthrodesis, osteotomies or fractures in hand or foot surgery :**
- Fixation of small bone fragments, in long bones or small bones fractures.
- They can be used alone, or as a fixation mean of other implants (plates, ankle prosthesis...)

3 - Contraindications:
The implant should not be used in a patient who has currently, or who has a history of:
- Local or systemic acute or chronic inflammation;
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Note: Certain solutions such as those containing bleach or formalin may damage the devices, and they must not be used. Use of metallic brushes or other abrasive products is also forbidden.
Cleaning should be immediately followed by profusely rinsing with deionized water. Check that water flows out the cannulated parts.
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If necessary, repeat the full process or proceed to a manual cleaning.
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Drying: Drying temperature should not exceed 80°C.
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The following two methods have been validated by the manufacturer and can thus be used:

Method: steam	Method: steam
Cycle: wrapped gravity	Cycle: wrapped gravity
temperature: 132°C	temperature: 134°C
Exposure time: 45 minutes	Exposure time: 18 minutes

Other sterilization method and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques.
EtO sterilization or cold sterilization techniques are not recommended.

7 - Use of the implant:
The surgeon must use the instrumentations recommended in accordance with the operative technique available from the manufacturer. The medical device must be used in compliance with the use of the profession and the standard of art. Do not attemp a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.
Opening of the instruments set must be done according to aseptic condition.
When handling the implants, avoid any contact with other material or tools which may damage the implant surface. Under no circumstances should the implant be modified .

8 - Re-use of the implants:
Orthopedic implants already implanted must never be re-used. The company accepts no responsibility for such re-use.

9 - Re-sterilization of non implanted products:
Re-sterilization is only allowed for non implanted products.
The implants can be sterilized several times in the same conditions as those described in paragraph 6.

10 - Preventative actions for the patient to avoid post-operative complications:
- Avoid extreme position such as flexion-extension
- Wear orthopedic shoes according to the surgeon's prescription
- Receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

11 - Storage: Store in dry place

12 - Liability:
Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product.
Newdeal neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product.
Newdeal intends that this device should be used only by physicians having received appropriate training in orthopedic surgery techniques.

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

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION: Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

HALLU®-FIX ARTHRODESIS SET
INSTRUCTIONS FOR USE
HALLU®-REAM

SURGICAL INSTRUMENTS TO BE CONNECTED TO AN ACTIVE DEVICE

In accordance with EEC directive 93/42 relative to medical devices, this product must be handled and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

These instruments are intended for use in surgery, and should be used only for the introduction of associated Newdeal products.
None of the instruments should be implanted.
Only medical professionals who are thoroughly familiar with the instruments function, application, and use should use them in surgery.
Only a surgeon qualified to perform the orthopedic surgery required by the particular patient should use the surgical instruments.
Unless labeled for single use, this instrument may be re-used. However, active surgical instruments have a limited lifespan.
Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose, or even dangerous to the patient or surgical staff.

Handling and Reprocessing:
This product is sold non-sterile.
Check the integrity of the packaging and labeling before opening the packing.
Remove all the products from their packaging prior to sterilization .
All products should be cleaned, decontaminated, and sterilized before use.
Always immediately clean and decontaminate all devices that have been soiled.
Repeated reprocessing has little effect on these products.
Preparation: Double instruments (ex. Internal screwdriver and associated external screwdriver) should be separated prior to cleaning.
Cleaning: Cleaning can be performed manually, automatically or ultrasonically in accordance with the specifications designated by the manufacturer of the hospital's equipment.
Manual cleaning: Manual cleaning consists of using neutral cleaners, applied with a soft brush, taking special care to threaded parts and parts difficult to reach.
Note: Certain solutions such as those containing bleach or formalin may damage the devices, and they must not be used. Use of metallic brushes or other abrasive products is also forbidden.
Cleaning should be immediately followed by profusely rinsing with deionized water. Check that water flows out the cannulated parts.
Automatic cleaning: Automatic cleaning is performed in a cleaning/disinfecting machine using neutral cleaners, with a cleaning cycle of 5 minutes minimum and a rinsing cycle of 3 minutes.
Check the complete removal of visible dirt, especially in the cannulated parts.
If necessary, repeat the full process or proceed to a manual cleaning.
Disinfection: If an automatic cleaning is used, final rinsing at 80°C during 10 minutes can be performed.
Drying: Drying temperature should not exceed 80°C.
Packaging: No specific requirements.
Sterilization: Newdeal's implants and instruments are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital.

The following two methods have been validated by the manufacturer and can thus be used:

Method: steam	Method: steam
Cycle: wrapped gravity	Cycle: wrapped gravity
Temperature: 132°C	Temperature: 134°C
Exposure time: 45 minutes	Exposure time: 18 minutes

Other sterilization method and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques.
EtO sterilization or cold sterilization techniques are not recommended.

Examination:
Instruments must always be examined by the user prior to use in surgery.
Examination should be thorough, and in particular should take into account the presence of any cracks, bending, or distortion, and that all components of the instrument are complete.
Never use instruments with obvious signs of excessive wear, damage, incomplete or otherwise unfunctional.

Safety:
Safety glasses are recommended when using any active surgical instrument.
The cannulated active surgical instruments should not be used without the appropriate corresponding Newdeal K-wire inside the cannulated part.
The K-wire must be renewed for each procedure.
The active surgical instruments should not exceed the recommended speed of the instrument manufacturer's specifications (1500 revs/minute).
The surgeon using the active surgical instrument is responsible for the proper operation of the instrument as well as any accessories or equipment, including power equipment, that may be necessary for the use of the active surgical instrument.
Avoid using excessive force, twisting, or bending of the active surgical instrument in any unnatural or unintended way.
The active surgical instrument must be properly inserted and securely locked into the proper instrument before the instrument is turned on and/or operated.
All accessories must be properly inserted, sealed, and locked before turning on and/or engaging the active surgical instrument.
The active surgical instrument may become hot from friction and the surgeon should take appropriate care to ensure that the patient is not harmed.
Minimize the tissue contact to avoid possibility of burns.
The active surgical instrument must not be used for any purpose other than its intended use in the orthopedic surgical procedure.
The active surgical instrument must not be modified.
Resharpening of active surgical instrument should not be performed under any circumstances.
Contact with other metal objects could cause damage to the active surgical instrument and may necessitate replacement.
Newdeal informs the surgeon that repeated uses of the active surgical instrument can lead to incidents which would compromise the surgical technique or the results of the procedure.

Responsibility of the Surgeon :
Newdeal does not practice medicine and does not recommend any specific surgical technique.
It is the surgeon's responsibility to select the appropriate surgical technique and instruments for each individual patient, in accordance with the surgeon's practice, experience, training, standard of care and knowledge of the relevant medical literature.
Newdeal is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
Criteria for patient selection is the responsibility of the surgeon. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and device being implanted in the surgical procedure. The surgeon should refer to the instructions for use accompanying the device.
Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.

Limitation of Liability:
Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Newdeal neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Newdeal intends that this device should be used only for the introduction of associated Newdeal products by physicians having received appropriate training in orthopedic surgery technique.

Information:
Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

HALLU®-C PLATE

Catalog Number				Description
117 340ND	• Size 1	• 4 holes	• 40 mm	• Right
117 345ND	• Size 2	• 5 holes	• 45 mm	• Right
117 350ND	• Size 3	• 6 holes	• 50 mm	• Right
117 440ND	• Size 1	• 4 holes	• 40 mm	• Left
117 445ND	• Size 2	• 5 holes	• 45 mm	• Left
117 450ND	• Size 3	• 6 holes	• 50 mm	• Left

HALLU®-S PLATE

Catalog Number				Description
117 150ND	• Size 1	• green	• 50 mm	• Right
117 155ND	• Size 2	• yellow	• 55 mm	• Right
117 160ND	• Size 3	• blue	• 60 mm	• Right
117 250ND	• Size 1	• green	• 50 mm	• Left
117 255ND	• Size 2	• yellow	• 55 mm	• Left
117 260ND	• Size 3	• blue	• 60 mm	• Left

HALLU®-REAM

Catalog Number		Description
129 714ND	• Metatarsal reamer •	Diam. 14 mm
129 716ND	• Metatarsal reamer •	Diam. 16 mm
129 718ND	• Metatarsal reamer •	Diam. 18 mm
129 720ND	• Metatarsal reamer •	Diam. 20 mm
129 724ND	• Phalangeal reamer •	Diam. 14 mm
129 726ND	• Phalangeal reamer •	Diam. 16 mm
129 728ND	• Phalangeal reamer •	Diam. 18 mm
129 730ND	• Phalangeal reamer •	Diam. 20 mm

HALLU® SNAP-OFF

Catalog Number		Description
STANDARD Diam. 2.7 mm		
117 012ND	• Snap-off screw •	length 12 mm
117 014ND	• Snap-off screw •	length 14 mm
117 016ND	• Snap-off screw •	length 16 mm
117 018ND	• Snap-off screw •	length 18 mm
117 020ND	• Snap-off screw •	length 20 mm
117 024ND	• Snap-off screw •	length 24 mm
117 028ND	• Snap-off screw •	length 28 mm
FAT BOYS Diam. 3.0 mm		
117 112ND	• Snap-off screw •	length 12 mm
117 114ND	• Snap-off screw •	length 14 mm
117 116ND	• Snap-off screw •	length 16 mm
117 118ND	• Snap-off screw •	length 18 mm

ASSOCIATED INSTRUMENTS

Catalog Number	Description
115 100ND	K-wire diam. 1.0 mm - length 100 mm
115 216ND	K-wire diam. 1.6mm - length 150mm - 2 sharp tips
119 618ND	Drill Diam. 1.9 mm
129 731ND	Hallu®-C plate bender left
129 732ND	Hallu®-C plate bender right
129 733ND	Cannulated screwdriver
129 734ND	Drill guide 1.9 mm
129 736ND	Depth gauge
129 930ND	Sterilization container

- The products are manufactured and referenced within the frame of the standards in force.
- Implantation procedures are described in the surgical technique.
- Non-contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- WARNING: Federal law (USA) restricts this device to sale by or on the order of a physician.

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