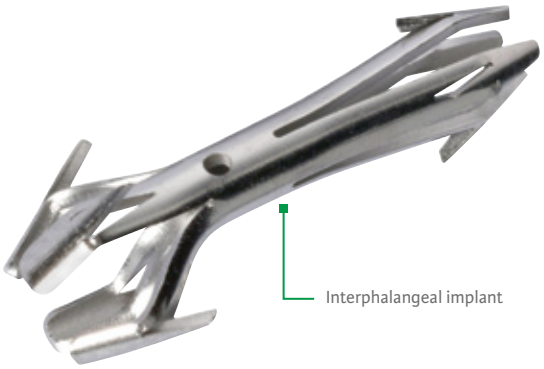
Integra™

Ipp-On®

Intramedullary guide for PIP stabilisation

SURGICAL TECHNIQUE

INTEGRA™
LIMIT UNCERTAINTY



Indications

The IPP-ON® implant is intended for fixation of proximal interphalangeal joint arthrodesis of the lesser toes.
Examples include:

- Rigid or even semi-rigid claw toe
- Revision in the case of failed arthrodesis or arthroplasty
- 2nd toe shortening

Concept

Proximal interphalangeal joint stabilisation is difficult to perform if a certain degree of plantar flexion is ideally desired in order to respect the anatomy and kinetics of the toe. Few implants on the market today are able to fully respond to the demands of this surgery.
The IPP-ON® intramedullary guide has been developed to respond to:

Anatomical constraints:

- Adapted sizing and angulation
- Effective cortico-cancellous anchoring

The need for ease of implanting:

- Simple ancillary instrumentation and ease of use

Achievement of a good stabilisation:

- The double bipolar anchoring contributes to the inter-fragmentary impaction

Implantation of the IPP-ON® interphalangeal implant therefore forms part of the therapeutic response to interphalangeal stabilisation and constitutes an innovative solution.

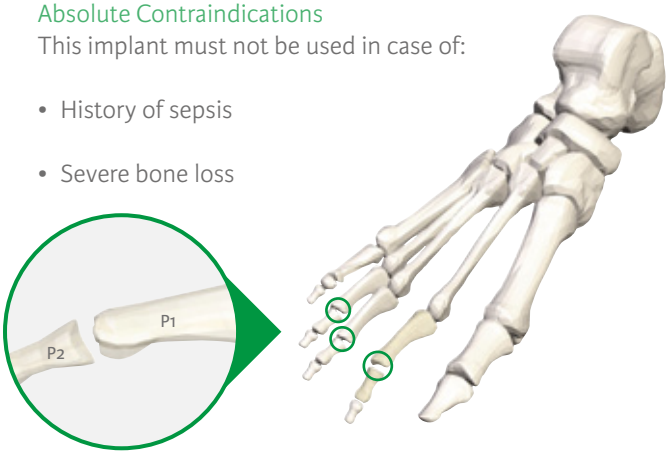
Contraindications

Technical limits
It may not be possible to insert this intramedullary guide in case of:

- Too great deformity
- Neurologic deformities
- PIP and DIP deformities on the same toe
- Too short toe
- Too big toe
- Osteoporotic bone

Absolute Contraindications
This implant must not be used in case of:

- History of sepsis
- Severe bone loss



NEWDEAL, the manufacturer of this device, does not practice medicine and does not under any circumstances recommend this particular technique or any other surgical technique for use on a specific patient. The surgeon who performs the implant procedure is solely responsible for determining and using the appropriate techniques for each patient.

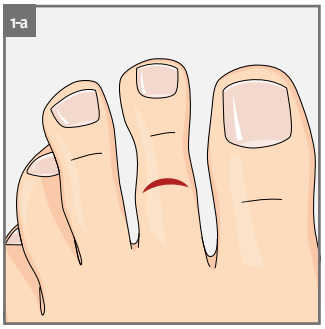
Surgical Technique

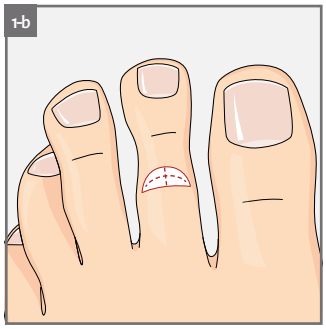
Surgical Site Preparation

Caution: use x-rays to ensure that the implant is suitable for adaptation to the joint concerned (corticals too thin, diaphysis step very wide or too narrow).

1 Incision: approach

- A transversal dorsal incision (as shown in *Fig. 1-a*) allowing for excision corn where applicable *(Fig. 1-b)* or a longitudinal dorsal incision for better exposure
- Joint exposure in the normal fashion after complete arthrolysis
- Plantar flexion of the distal phalanx





2 Joint preparation

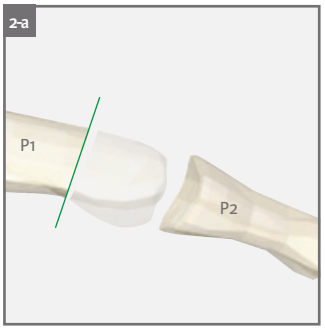
Two cuts are made by means of a saw or a rongeur, respecting the predefined angles:

PROXIMAL

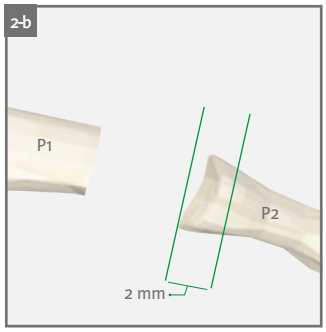
The head of P1 is completely resected. *(Fig. 2-a)*

DISTAL

Next, a 2 mm thick cut is performed with resection of the cartilage and the subchondral bone thereby exposing the cancellous bone. *(Fig. 2-b)*

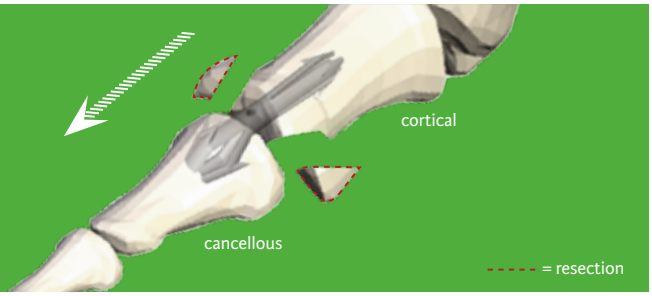


Proximal cut



Oblique distal cut

TIP
To increase the P1-P2 inter-fragmentary penetration in case of toe shortening, resect the medial and lateral corners of the distal P1 extremity, to enable a better fit for stabilisation.



239 011 and 239 012
distal and proximal
hand drills – size 1

239 021 and 239 022
distal and proximal
hand drills – size 2

239 500
clamp holder

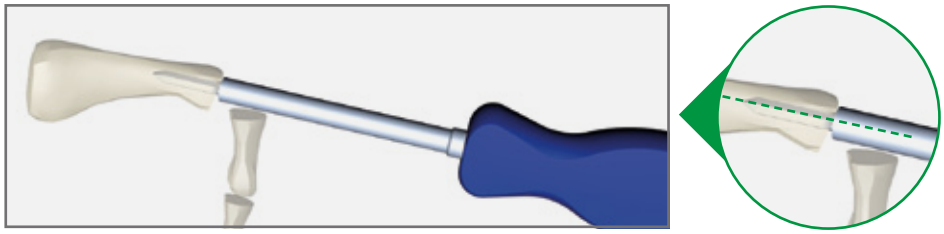
239 030
handle holder

3 Preparation of the proximal phalanx and determining the size of the implant

Conform the proximal diaphysis using the size 1 hand drill (239 012). If the insertion is sufficient (contact with the corticals) the size 1 implant should be chosen. If this is not the case, use the size 2 hand drill (239 022) which limits the choice to the size 2 implant (230 002S).

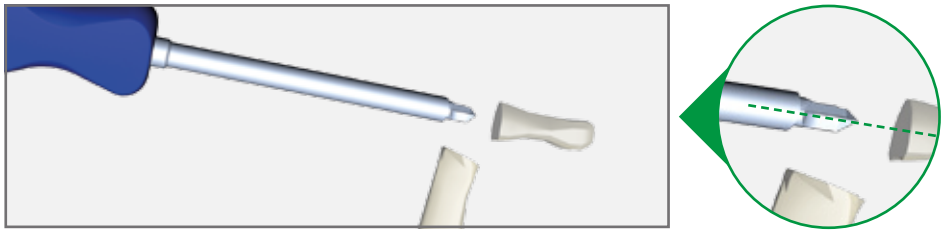
TIP
Statistically, size 1 corresponds to a woman and size 2 to a man.

TIP
If the insertion of the size 1 hand drill is difficult, start reaming using a minimally invasive burr type instrument (Ø 1.9mm) or a K-wire (Ø 1.9mm).



4 Preparation of the distal phalanx

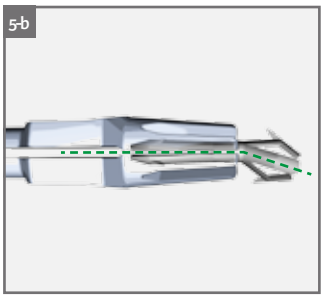
The distal phalanx is then conformed using the hand drill corresponding to the size of implant chosen (239 011 or 239 021).



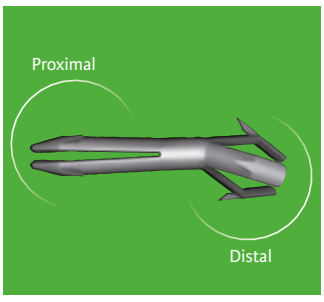
5 Prehension of the IPP-ON® implant

Open the sterile packaging and use the clamp (239 500) to grip the centre of the implant *(Fig. 5-a)*. Then insert the implant into the purpose-built handle (239 030) *(Fig. 5-b)*.
Insert the proximal part of the implant into the holder extremity until the end point is reached *(Fig. 5-c)*; the dorsal part must be identified by means of the landmark in order to respect the flexion of the implant.

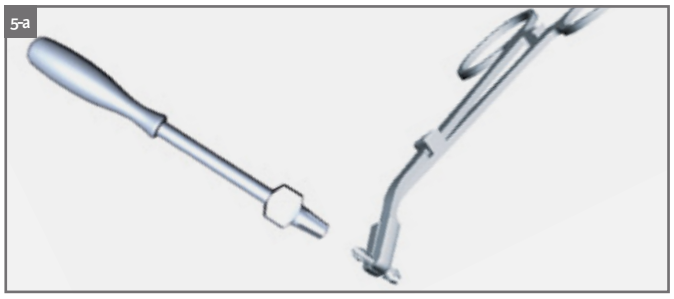
5-b



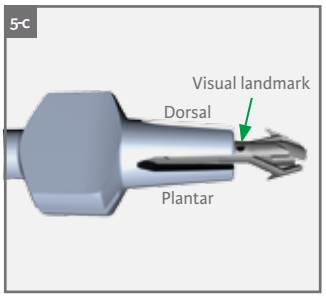
Downward anatomical angle



5-a



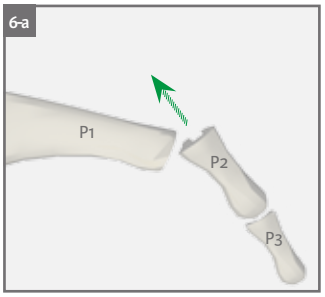
5-c



6 Distal part insertion of the implant

To best expose the base of P2, you are advised to dorsally sublux P2 over P1 to be able to visualise the insertion of the implant without soft tissue obstructing the view. *(Fig. 6-a)*.
Firstly, the implant is anchored into distal phalanx P2 by pressing on the proximal part of the holder until the holder comes into contact with the bone (visual landmark). *(Fig. 6-b)*
The handle is then removed by letting up the pressure, the implant stays in place. *(Fig. 6-c)*

6-a

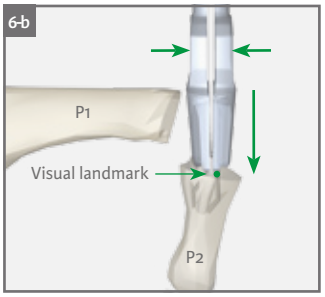


Subluxation

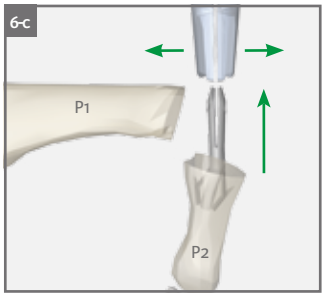
Note
Be sure that the implant is easily/ freely inserted in the holder.

TIP
If the introduction seems difficult, use a size 2 distal hand drill for the ostium, to make the implant easier to introduce. This doesn't affect the distal anchorage.

6-b



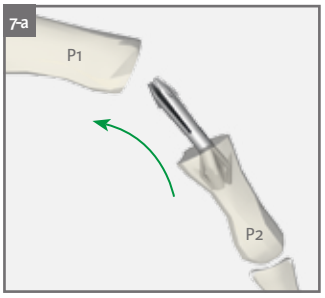
6-c



7 Proximal part insertion of the implant

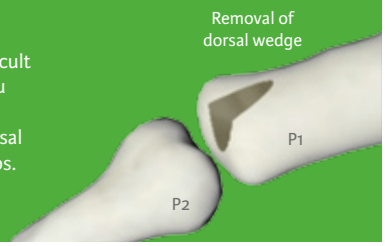
The proximal part is inserted into phalanx P1 using a swinging movement, as shown in the image. *(Fig. 7-a)*.
Phalanxes P1 and P2 are brought into contact by impaction (by hand). *(Fig. 7-b)*
Ensure that the bony surfaces come into contact. The axial or rotational stability can be checked without applying too much force. *(Fig. 7-c)*

7-a

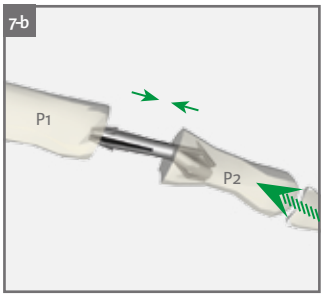


TIP
Insertion into the P1 phalanx can be performed using clamp holder (239 500) or thinner Mosquito type forceps.

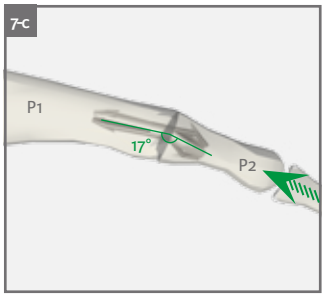
TIP
If insertion into P1 is made difficult by a too small proximal cut, you should either perform another cut (cf. step 2), or remove a dorsal wedge using Liston type forceps.



7-b



7-c



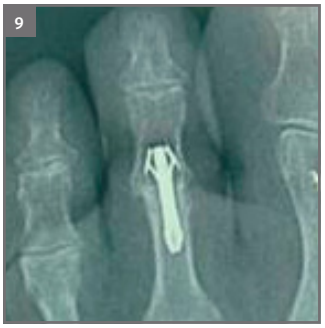
8 Closure

For a better primary stability during the first 3 weeks, it is recommanded to close the capsule, to suture the extensor tendon and to perfom a syndactyly.

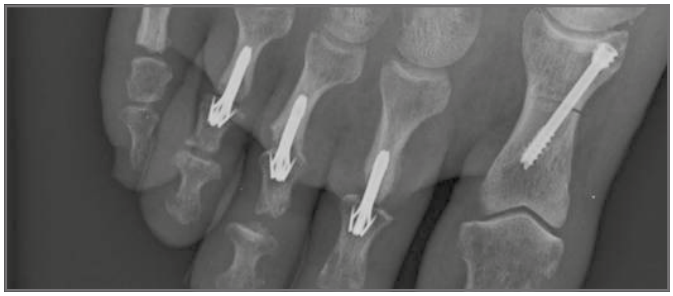
9 X-Ray control

To ensure proper contact between the 2 phalanxes, it is recommended to check the assembly of the system using fluoroscopy.

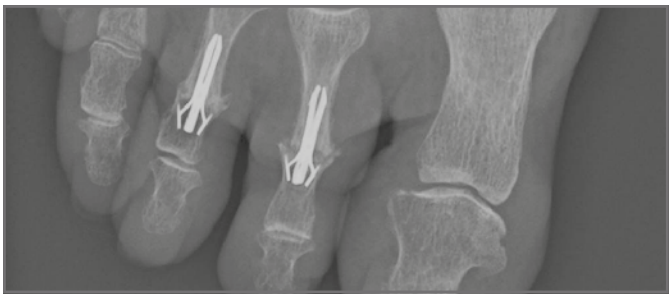
9



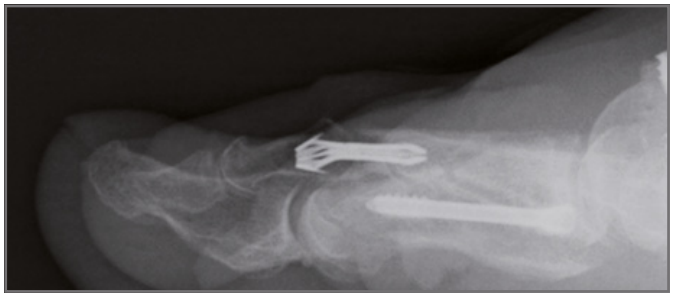
X-rays



Immediate post-operative



2 months post-operative

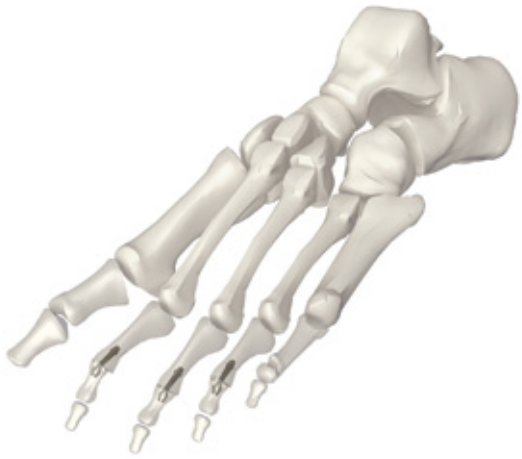


Immediate post-operative

Post-operative instructions

Usual post-operative protocol for forefoot surgery.
It is important to control the toe bearing.

- No specific post op care because of suture together
- Weekly dressing for one month
- No physiotherapy
- Post op shoes: one month



Removal procedure

In case of non-union

- use the same approach
- open the joint
- expose the implant and the two bone parts
- distract the 2 phalanges
- remove the implant with the clamp holder
- The surgeons must pull hard because the 2 anchors hold the implant

In case of a mal union (with fusion)

The protocol remains the same except for one step: the surgeon needs to perform a corticotomy in order to reach the implant and give mobility to the system for implant removal.

Caution
In other cases, the surgeon can cut the implant in order to grip each side of the implant by means of extraction forceps for “a higher extraction” if necessary.

Instructions for use

IPP-ON® • SINGLE USE

In accordance with the 93/42/CEE directive regarding medical devices and their amendments, this product must be handled and/or implanted by TRAINED and QUALIFIED individuals WHO HAVE READ these INSTRUCTIONS.

Description

The IPP-ON® arthrodesis implant is intended for the proximal interphalangeal joint and exists in different sizes.
The IPP-ON® implant is made of stainless steel 316L in accordance with standard ISO 5832-1 / ASTM F138 & F139. These medical devices do not contain phthalates unless indicated otherwise on the label.

Indications

The IPP-ON® implant is indicated for use in fixation of arthrodesis of the proximal interphalangeal joint, particularly in the case of:
- rigid or semi-rigid claw toe,
- revision surgery in the case of failure of arthrodesis or arthroplasty,
- shortening in the case of an excessively long second toe.

Use x-rays to ensure that implant is able to be adapted to the joint concerned. In the case of corticals which are too thin, a diaphysis which is very wide or too narrow, a very soft or hard bone, implantation of this implant is not recommended.

Contraindications

The implant must not be implanted in a patient who has currently or has a history of:
- active local or systemic infection
- severe peripheral vascular disease
- severe longitudinal deformity
- insufficient quantity or quality of bone to permit stabilisation of the arthrodesis
- conditions which restrict the patient's ability or willingness to follow the postoperative instructions during the healing process
- suspected or documented metal allergy or intolerance

Use radiographs to ensure that implant is able to be adapted to the joint concerned. In the case of corticals which are too thin, a diaphysis which is very wide or too narrow, a very soft or hard bone, implantation of this implant is not recommended.

Warnings

Serious post-operative complications may occur from use of this implant in a patient who:
- lacks good general physical condition;
- has severe osteoporosis;
- demonstrates physiological and physical anomalies which may cause postoperative complications;
- has immunological reactions, sensitisation or hypersensitivity to foreign objects;
- systemic or metabolic deficiencies.

These implants are intended to act as a guide during the bone healing process, and not to replace normal bone structure or to support the weight of the body in the existence of incomplete bone healing. Delayed fusion, or a lack of fusion, associated with weight bearing may possibly cause rupture of the implant due to metal fatigue. Implantation of this implant is not recommended in the case of corticals which are too thin, a diaphysis which is very wide or too narrow or a very soft or hard bone.

Precautions for use

The practitioner must determine whether the implant is appropriate for patients who have any of the following conditions:
- Drug and/or alcohol and/or tobacco addition or abuse;
- Infectious diseases;
- Signs of malignancy;
- Local bone tumours;
- Compromised wound healing;
- Obesity;
- Psychological instability, demonstrates a lack of understanding, demonstrates inappropriate motivation or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
- Lack of understanding of the nature of the metal implant, which is not as strong as normal healthy bone, and may bend, loosen or break if excessive demands are placed on it;
- Lack of understanding that their preoperative capacity may not be fully recovered even after successful implantation.

Knowledge of surgical techniques, proper bone reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.
Criteria for patient selection are the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process.
Determination of the appropriate indications and contraindications and the selection of 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.
Prior to surgery the surgeon should discuss with the patient possible surgical 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 risk/benefit relationship and the advantages in light of the patient's state of health and the surgeon's practice, training, experience, and knowledge of the relevant medical literature.
Complications associated with the use of osteosynthesis systems have been reported in the medical literature.
Any patient undergoing a surgical procedure may be subject to intra-operative and post-operative complications.
Each patient's tolerance to surgery, a medication, and implantation of a foreign object may be different.
Possible risks, adverse reactions, and complications associated with the surgery and the use of the osteosynthesis systems should be discussed with and understood by the patient prior to surgery.
The implant is composed of metal alloys; therefore, it may subject to reactions and complications, including those listed herein. The patient should not be led to hold 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 ALL OF THIS INFORMATION PRIOR TO SURGERY.
The most commonly encountered complications and side effects are:
- Bending, loosening, and/or breaking of the components
- Loss of fixation to the bone
- Shortening of the limb, or loss of anatomical position, associated with an absence of fusion or poor fusion with rotation or angulation
- Deep or superficial infection
- Injury due to irritation of tissues
- Sensitivity, or other reaction to the device material
- Reactions in the tissue adjacent to the implants, including macrophagic reactions or reactions to a foreign object
- Pain, discomfort, or abnormal sensations linked to the presence of the implant
- Haematoma or thrombosis.

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:
IRM/SCANNER: ask the patient to systematically mention that he/she has metallic material implanted.

Packaging - sterility

This product is sold either sterile or non-sterile.
The method of sterilisation is mentioned on the packaging. Elements sterilised by radiation are exposed to a minimum of 25 kilograys of gamma radiation.
If the product does not carry the specific designation "STERILE", it must be sterilised before use, in accordance with the regulations in force.
If the product has been removed from the packaging but not used, it must be re-sterilised.
Check the integrity of the packaging and labelling before opening the packaging. Sterilisation is guaranteed as long as the packaging has not been damaged or opened and the expiry date has not passed.
Do not use the product if the packaging has been opened or damaged outside of the operating theatre.
The internal packaging must be handled in sterile conditions (people/instruments).

Use of the products

The surgeon must use the instruments recommended in accordance with the surgical technique provided by the manufacturer. The medical device must be used in compliance with the normal usages of the profession.
The correct selection of components is extremely important. The type and size must be selected for the individual patient. Not using the largest components possible or imperfect positioning of the implant, may result in bending, loosening, and/or breakage of the components, the bone, or both. It is advisable to ensure that the adequate implant, of an appropriate size, is used with the suitable instruments. Implants manufactured by Newdeal must not be used with elements made by another manufacturer, given that these components are not compatible. Precise preoperative planning should be routinely carried out, on the basis of the radiographic data. Templates are available for this purpose. Do not attempt a surgical procedure with damaged, suspect or faulty instruments. Inspect all components preoperatively to assure utility. Alternative fixation methods should be available intra-operatively.
Opening of the instrument box must be performed in aseptic conditions.
When handling implants, avoid all contact with other material or tools which may damage the implant surface. Under no circumstances should the implant be modified.
Multi-component devices manufactured by Newdeal (such as the plate-screw systems) must only be used with appropriate products manufactured by Newdeal and should under no circumstance be used in conjunction with components made by other manufacturers, which may not be compatible. The company disclaims all responsibility in the event that these instructions are not followed.

Re-use of the products

Orthopaedic implants which have already been implanted must never be re-used. Such re-use could alter the characteristics and performance of the implant, increasing the likelihood of the complications and/or side effects described above. The company accepts no responsibility for such re-use.

Re-sterilisation of non-implanted products and sterilisation of non-sterile products

Unless the product is supplied sterile and clearly labelled as such, all implants and instruments must be sterilised by steam before use. Re-sterilisation is only permitted for non-implanted implants. Implants considered to be non-sterile can be re-sterilised out of the packaging before implantation in accordance with the standards in force in the country.
Newdeal recommends that the implants be sterilised by steam in an autoclave of the type routinely used in hospitals. The implants may be sterilised several times in the same conditions as described here.
The two following methods have been validated by the manufacturer and can thus be used:
Newdeal® sterilisation container in stainless steel:

Cycle: Gravity displacement, 5 pulses [Maximum 900 mbar;
Minimum 200 mbar]
Minimum temperature: 134°C
Exposure time: 18 minutes
Drying: 20 minutes
Cycle: Pre-vacuum, 3 pulses [Maximum 2.8 bar; Minimum 339 mbar]
Minimum temperature: 132°C
Exposure time: 4 minutes
Purge: 2-3 minutes
Drying: 20 minutes

These sterilisation parameters imply that all of the instruments have been correctly cleaned before sterilisation. The parameters are valid for the sterilisation of the specific configurations indicated by the marking in the container. If other products are added into the box or into the container, the recommended parameters may not prove to be valid, and new cycle parameters must be validated by the user. The autoclave must be correctly installed, maintained and calibrated.
Other sterilization method and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate their own method using appropriate laboratory techniques.
Ethylene oxide sterilisation or cold sterilisation techniques are not recommended.

Information regarding postoperative treatment

The patient must be informed that a second intervention, of a lesser magnitude, is usually necessary for removal of the device.
It is the responsibility of the surgeon to decide whether or not to remove the device. However, in any instance where removal is possible and practical for the patient in question, fixation devices should be removed once they have fulfilled their role of aiding healing. In absence of bursa or pain, removal in older patients is not recommended.
The postoperative instructions given to the patient, as well as nursing care are critical. Premature weight bearing significantly increases the demands placed on the implant and consequently the risks of loosening, bending or breakage of the implant. Obese or non-collaborative patients, as well as those who might be susceptible to delayed fusion or a lack of fusion should receive additional support.
Even after completely healed, the patient must be warned of the fact that re-fracture is more likely with the implant in place or shortly following its removal than later when the spaces left empty in the bone by the removed implant have been completely refilled.
The patient must be warned against any unassisted activity which involves walking or weight handling.
The postoperative follow-up and care must be structured in order to avoid any weight bearing on the operated extremity while stability is being established.
The patient should be encouraged to inform his/her surgeon of any unusual change in the operated extremity. If bending of the implant is suspected (unusual pain and progressive change in the radiographs), an intensified programme of visits and checks in advised, and new warnings and instructions can be communicated to the patient regarding the new activity restrictions.
The patient should be encouraged to seek urgent treatment in case of infection in the operated limp or elsewhere on the body.

Storage

Store the implants in a dry place.

Information about the products / Liability

Newdeal, a subsidiary company of Integra LifeSciences, has exercised reasonable care in the selection of materials and the manufacturing of these products and guarantees that these products are free from manufacturing defects. Newdeal excludes all other warranties, either express or implied, including, amongst others, any implied warranty of merchantable quality or fitness for purpose. Newdeal shall not be held responsible for any expense, damage or loss arising directly or indirectly from the usage of the product. Newdeal neither assumes, nor authorizes any other person to assume on its behalf, any additional liability or obligation in regard to these products. Newdeal restricts the use of this device to doctors who have received appropriate training in the techniques of orthopaedic surgery requiring the use of a device.

WARNING

This device is not approved for fixation or support in the posterior part of the vertebral bodies (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION

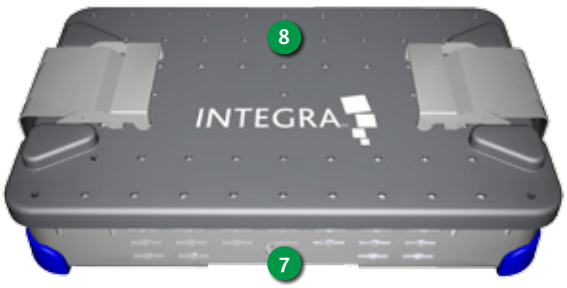
Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

All products are supplied, referenced and identified in compliance with the standards in force. The implantation conditions are described in the operating instructions. Non-contractual document. The manufacturer reserves the right to carry out, without prior notice, any modification aimed at improving the quality of its products.

Date of last revision: 10/07/2009.

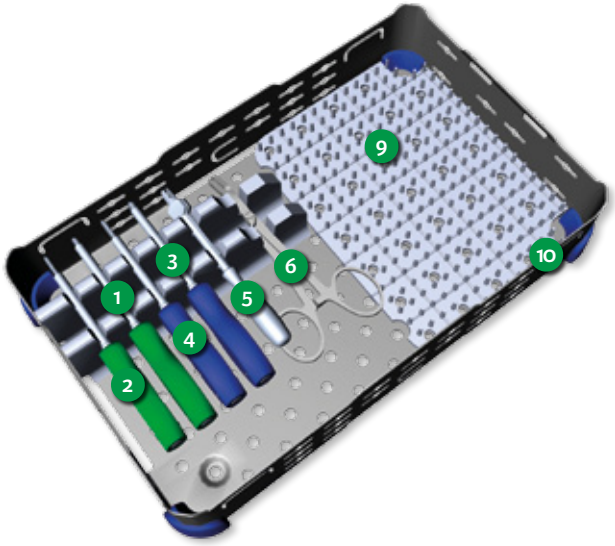
IPP-ON® Interphalangeal Implants

Reference	Description
230 001S	Sterile implant / Ipp-On® interphalangeal– size 1
230 002S	Sterile implant / Ipp-On® interphalangeal – size 2



Instruments

#	Reference	Description
1	239 011	Distal hand drill – size 1
2	239 012	Proximal hand drill – size 1
3	239 021	Distal hand drill – size 2
4	239 022	Proximal hand drill – size 2
5	239 030	Handle holder
6	239 500	Clamp holder



Container

#	Reference	Description
	239 000	Container including:
7	239 001	Basis
8	996 100	Lid
9	278 902	Mat
10	119 909	Blue silicone wedge

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