IPP-ON™

Interphalangeal implant

newdeal®
New ideas for foot surgery™

Surgical Technique

ORTHOPAEDICS
LOWER
EXTREMITY

INTEGRA™

IPP-ON™

Rationale

The proximal interphalangeal fusion is a challenging surgery. The ideal is a plantar flexion to respect the toe kinetic and anatomy. Today, few implants fulfill the previous surgical requirements.

Thereby, Newdeal has developed **IPP-ON™** that gives an answer to :

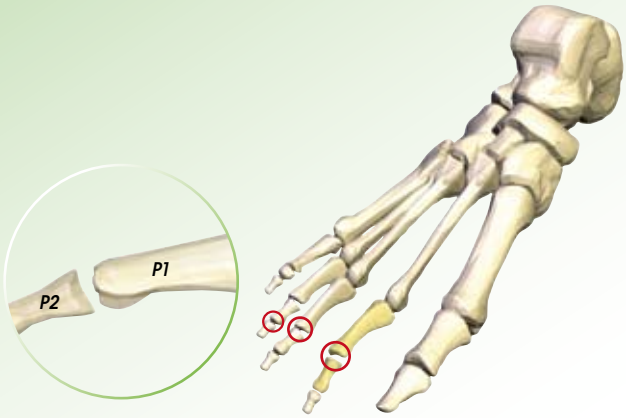
- <u>The anatomicals constraints</u>:
  - Adaptated size and angulation
  - Efficient cortico-spongious anchorage
- <u>The needs of an easy set up</u>:
  simple ancillary and easy to use
- <u>The reach of a good fusion</u>:
  the bipolar dual anchorage participates in the inter-fragmentary impaction.

The **IPP-ON™** implant is one of the most adaptated therapeutic for a proximal interphalangeal joint arthrodesis and constitutes an innovative solution.

Indications

The **IPP-ON™** implant respects anatomical plantar flexion for fixation of proximal interphalangeal joint arthrodesis in case of:

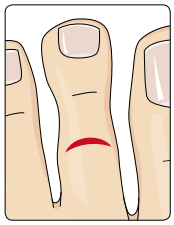
- rigid or semi-rigid hammertoe deformity
- revision of failed arthroplasty or arthrodesis
- 2nd toe shortening



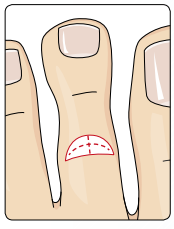
IPP-ON™ Surgical Technique

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

1 • Approach



– Transversal dorsal incision (as shown on the image).

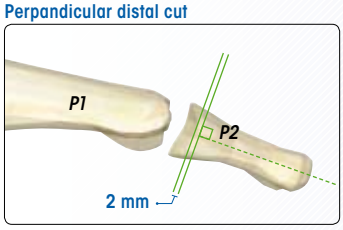


- Articular exposition according to the surgeon's habits (if horn presence, perform removal).
- Plantar flexion of the distal phalanx.

2 • Articular preparation

Two cuts are performed with a blade respecting the anatomic angles:

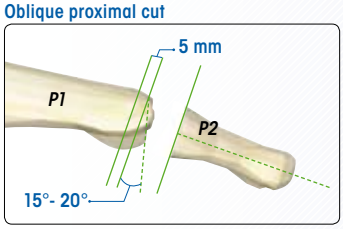
Perpandicular distal cut



<u>DISTAL</u> :

A 2 mm thickness distal cut is achieved in a perpendicular way to the axis of the second phalanx.

Oblique proximal cut



<u>PROXIMAL</u> :

A 5 mm thickness proximal cut is performed with an inclinaison of 15 - 20° compared with the previous cut.


239 012
PROXIMAL HAND DRILL - SIZE 1


239 011
DISTAL HAND DRILL - SIZE 1

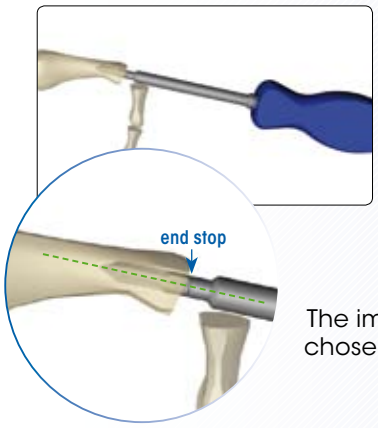

239 022
PROXIMAL HAND DRILL - SIZE 2


239 021
DISTAL HAND DRILL - SIZE 2


239 500
CLAMP HOLDER


239 030
HANDLE HOLDER

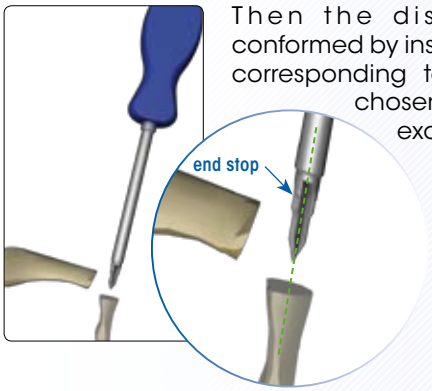
3 • Proximal phalanx preparation and size definition of the implant



Firstly, prepare the proximal diaphysis thanks to the hand drill size 1 ***(ref 239 012)*** inserted up to the end stop. If the cortical anchorage is enough, we choose the implant size 1 ***(ref 239 001S)***. If not, use proximal hand drill size 2 ***(ref 239 022)***.

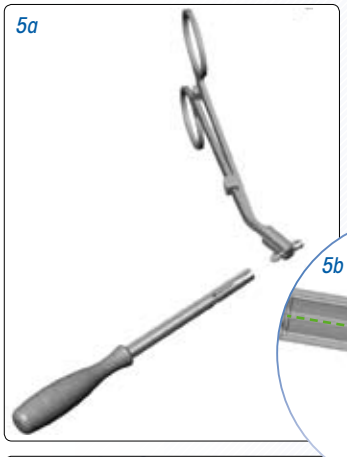
The implant size 2 ***(ref 239 002S)***, is so chosen.

4 • Distal phalanx preparation

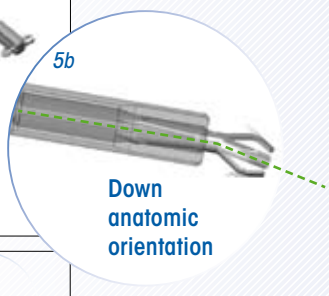


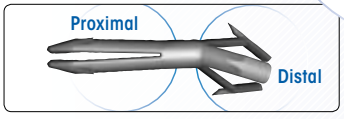
Then the distal phalanx is conformed by inserting the hand drill corresponding to the implant size chosen, taking care of not exceed the end stop.

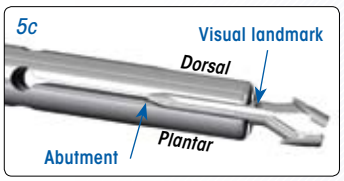
5 • Prehension of Ipp-On™ implant



Open the sterile packaging and hold the implant thanks to the clamp ***(ref 239 500)*** at its center *(5a)*, then place it in the holder extremity ***(ref 239 030)*** *(5b)*.

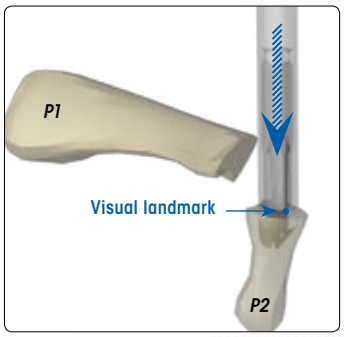




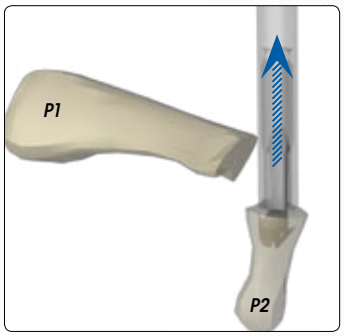


Insert the proximal part implant up to the end stop in the holder extremity *(5c)*; the dorsal part is identified with the landmark.

6 • Distal part insertion of the implant

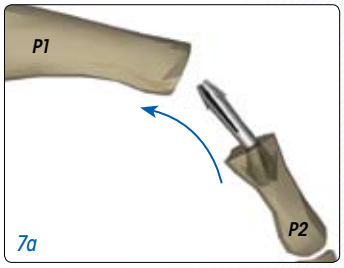


At the begining, anchor the implant in the distal phalanx P2 up to the holder contact with the bone.

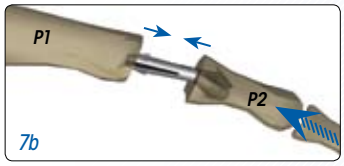


The holder is then removed, the implant remains in place.

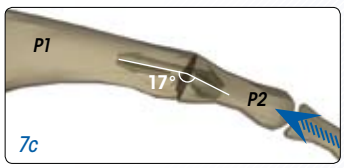
7 • Proximal part insertion of the implant



The proximal part is inserted in the phalanx P1 by swing, as shown on the image *(7a)*.



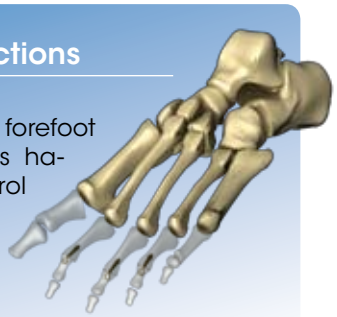
Bring together the two phalanxs P1 and P2 by impaction (with the hands) *(7b)*.



Take care of the bones close contact *(7c)*.

Postoperative instructions

Usual postoperative protocol of forefoot surgery according to surgeons habits. The toe bearing visual control is important.



IPP-ON™
Instructions for use

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

Description
The IPP-ON implant for arthrodesis is designed for proximal interphalangeal joint and is available in different sizes.
It is made out of 316L stainless steel according to standards ISO 5832-1 and ASTM F138 &F139.

Indications
The IPP-ON implant is intended for fixation of proximal interphalangeal joint arthrodesis.
Examples include:
rigid or semi-rigid hammertoe deformity
revision of failed arthroplasty or arthrodesis
2nd toe shortening.

Contraindications
The implant should not be used in a patient who has currently, or who has a history of:
Active local or systemic infection
Severe peripheral vascular disease
Severe longitudinal deformity
Insufficient quantity or quality of bone to permit stabilization of the arthrodesis
Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process
Suspected or documented metal allergy or intolerance.

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.
These implants are intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue.

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;
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 are 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 systems have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intraoperative 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 osteosynthesis systems should be discussed with and understood by the patient prior to surgery. The implant is made from metallic alloys; 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.
The following are the most frequent adverse events :
Loosening, bending, cracking or fracture of the implant components
Loss of fixation in bone
Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation
Deep or superficial infection
Irritational injury of soft tissues, including impingement syndrome
Sensitivity or other reaction to the device material.
Tissue reactions which include macrophage and foreign body reactions adjacent to implants
Pain, discomfort, or abnormal sensations due to presence of the implant
Hematoma 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 refracture.
Interference risks during medical imaging:
MRI/SCANNER: ask the patient to systematically mention that he/she was implanted with a metallic device.

Packaging - sterility
This product is sold either sterile or non sterile.
The sterilization method is specified on the packaging.
Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation.
If the product is not labeled « STERILE», it must be sterilized prior to use, in compliance with current regulations.
If the product has been removed from packaging but not used, it may be re-sterilized.
Check packaging and labeling integrity before use.
The sterility is guaranteed as long as the packaging has not been damaged or opened and before the expiration date.
Do not use any implant for which the packaging has been opened or damaged outside the operating theatre.
Inner packaging should be handled under sterile conditions (persons/instruments).

Use of the products
The surgeon must use the instrumentation 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. The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking or fracture of the device or bone or both. Care must be taken that the correct and appropriate size implant is used in conjunction with the correct instrumentation. Implants manufactured by Newdeal must not be used in conjunction with those of any other manufacturer, as component parts may not be compatible. Careful preoperative planning on the basis of radiographic findings should be carried out routinely. Radiographic templates are available for that purpose.
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.
The multi-component devices (such as plates-screws systems) should only associate the appropriated Newdeal® or Surfix® products and should never be used in conjunction with components of any other manufacturers, as these products may not be compatible. The company accepts no responsibility for such use.

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

Re-sterilization of non-implanted implants and sterilization of non-sterile products
Unless supplied sterile and clearly labeled as such, all implants and instruments must be steam autoclaved prior to use in surgery.
Re-sterilization is only allowed for non-implanted products. Remove delivery packaging in compliance with current regulations to sterilize non-sterile products. Newdeal®'s osteosynthesis implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital.
The implants can be sterilized several times in the same conditions.
The following two methods have been validated by the manufacturer:
Newdeal® Stainless Steel sterilization trays
Cycle Type: Gravity Displacement, 5 pulses [Maximum 900 mbar; Minimum 200 mbar]
Minimum Temperature: 134°C (273° F)
Exposure Time: 18 minutes
20 minute vacuum drying
Cycle Type: Pre-Vacuum, 3 pulses [Maximum 26.0 psig (2.8 bar); Minimum 10 inHg (339 mbar)]
Minimum Temperature: 132°C (270° F)
Exposure time: 4 minutes
2-3 minute purge
20 minute vacuum drying
These sterilization parameters assume that all instruments have been properly decontaminated prior to sterilization. The parameters are validated to sterilize specific configurations as noted in the tray markings. If other products are added to the tray or to the sterilizer, the recommended parameters may not be valid and new cycle parameters may need to be validated by the user.
The autoclave must be properly 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 the alternative method using appropriate laboratory techniques. EtO sterilization or cold sterilization techniques are not recommended.

Information related to postoperative care
- The patient should be advised that a second more minor procedure for the removal of the implants is usually necessary
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
- Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending, or breaking the device.
Patients who are obese or non-compliant, as well as patients who could be predisposed to delayed or nonunion must have auxiliary support.
- Even after full healing, the patient should be cautioned that re-fracture is more likely with the implant in place and soon after its removal, rather than later, when the voids in the bone left by implant removal have been filled in completely.
- Patients should be cautioned against unassisted activity that requires walking or lifting.
- Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.
- The patient should be encouraged to report to his/her surgeon any unusual changes of the operated extremity.
If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs) an intensified schedule of check-ups is advised and new warning and instructions to the patient may be appropriate regarding further activity restrictions.
- The patient should be encouraged to receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

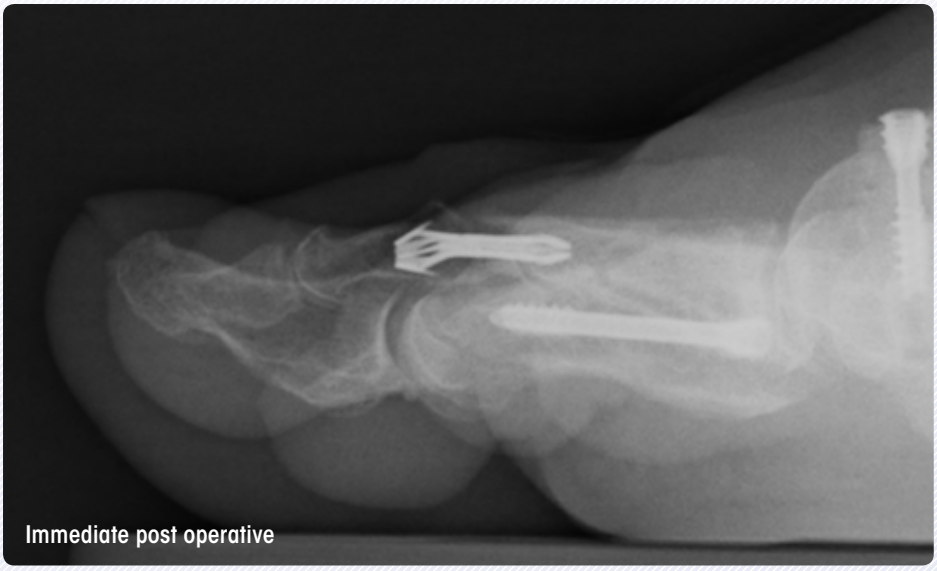
Storage
Store in dry place.

Product information disclosure / Liability
Newdeal®, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products. Newdeal® excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose.
Newdeal® shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Newdeal® neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Newdeal® intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

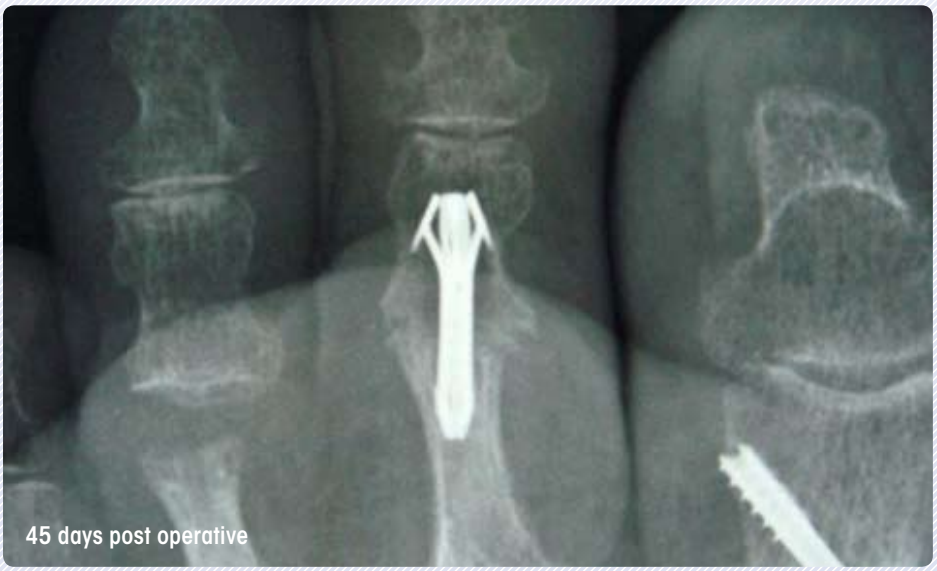
WARNING
This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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

X-Rays



Immediate post operative

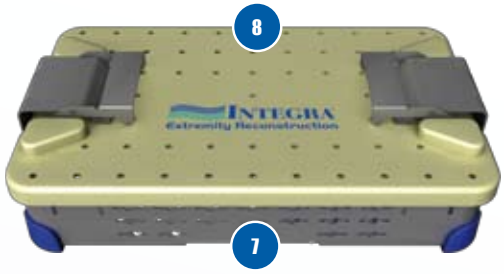


45 days post operative

IPP-ON™
Interphalangeal implant

INTEGRA™
Solution for foot surgery

Forefoot
Midfoot
Hindfoot
Ankle



Implants

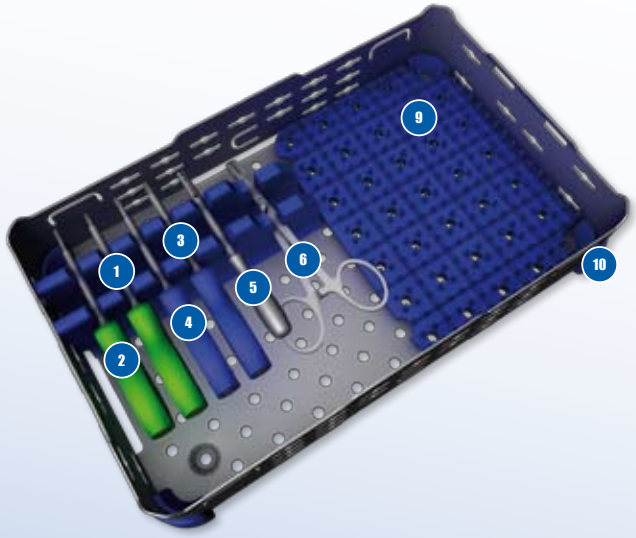
Ref	Description
230 001 S	STERILE IMPLANT / INTERPHALANGEAL IPP-ON™ - SIZE 1
230 002 S	STERILE IMPLANT / INTERPHALANGEAL IPP-ON™ - SIZE 2

Instruments

N°	Ref	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

Set = 239 000

N°	Ref	Description
7	239 001	BASIS
8	996 100	LID
9	278 902	MAT
10	119 909	BLUE SILICONE WEDGE



Distributed by

- Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region
- The products are manufactured and referenced within the frame of the standards in force.
- 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.
- Ipp-On, Newdeal, New ideas for foot surgery, and the Integra wave logo are trademarks or registered trademarks of Integra LifeSciences Corporation or its subsidiaries.

- *See Instructions for use*
- *Single use*
- *Sterile R* — STERILE | R

INTEGRA™
Integra LifeSciences Services (France) (Sales and Marketing)
66, quai Charles de Gaulle • 69463 Lyon Cedex 06 • FRANCE
✆+33 (0)4 37 47 59 00 • fax +33 (0)4 37 47 59 99
emea.info@Integra-LS.com • www.Integra-LS.com

Customer Services

France / International: +33 (0)4 37 47 59 10 • +33 (0)4 37 47 59 29 (Fax) • CustSvcFrance@Integra-LS.com
Benelux: +32 (0)2 257 4130 • +32 (0)2 253 2466 (Fax) • CustSvcBenelux@Integra-LS.com
Switzerland: +41 (0)2 27 21 23 30 • +41 (0)2 27 21 23 99 (Fax) • CustSvcSuisse@Integra-LS.com

newdeal®
New ideas for foot surgery™
Newdeal SAS
10, place d'Helvétie • 69006 Lyon • FRANCE
✆+33 (0)4 37 47 51 51 • fax +33 (0)4 37 47 51 52
newdeal@newdeal.info • www.newdeal.info

CE 0120