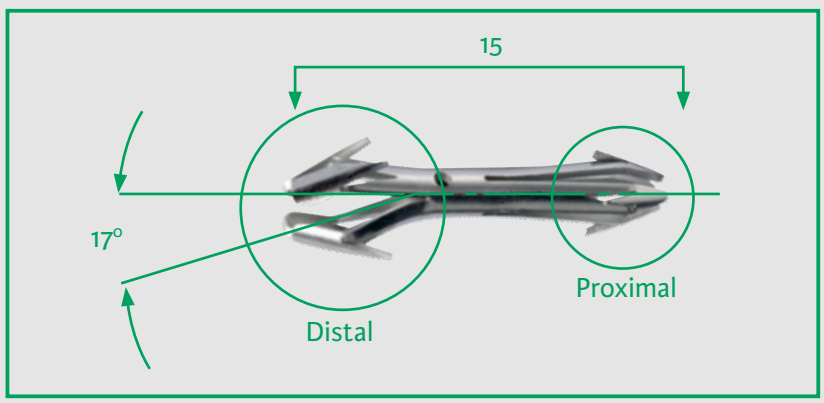
Integra®
IPP-ON® PIP Fusion System

The Integra® IPP-ON PIP Fusion System limits uncertainty by providing surgeons with an anatomically contoured implant that provides efficient cortico-cancellous anchorage.

- Adaptive design with proximal anchors designed specifically for cortical anchorage and distal anchors designed specifically for cancellous anchorage

- Anatomic angulation to address rigid or semi-rigid hammertoe in primary or revision cases

- One-piece design and straightforward instrumentation facilitate ease of implantation



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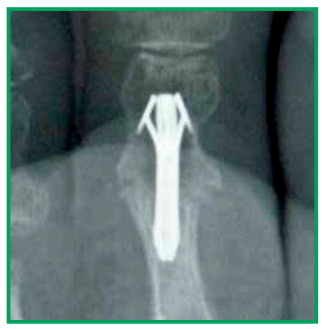
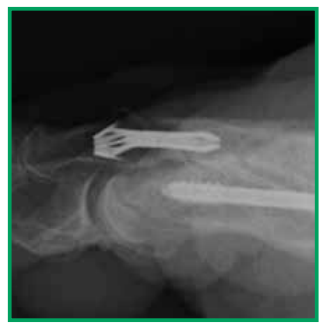
Indications

The Integra IPP-ON® PIP Fusion System is indicated for fixation of proximal interphalangeal arthrodesis of the lesser toes.



PIP Fusion System
AP View



PIP Fusion System
Lateral View

Examples include:

- Rigid or semi-rigid hammertoe deformity
- Revision of failed arthroplasty or arthrodesis
- Second toe shortening

System Description

The IPP-ON implant is designed for arthrodesis of the proximal interphalangeal joint. The implant is available in two different sizes. Sizing is determined by cortical contact in the proximal phalanx. The implants are made of 316L Stainless Steel.

The instrumentation is straightforward and comprised of proximal and distal hand drills and an implant holder.

System Features

When performing interphalangeal joint fusion it is difficult to recreate the appropriate plantar flexion angle to respect the anatomy and kinetics of the toe. Few implants on the market today are able to fully address the demands of this surgery. The Integra IPP-ON PIP Fusion System implant has been developed to address:

Anatomical constraints:

- Adapted sizing and angulation
- Effective cortico-cancellous anchoring

A simple surgical technique:

- Simple ancillary instrumentation and insertion technique

Warnings

Use x-rays to ensure that implant is able to be adapted to the joint concerned. In the case of cortical walls 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. Serious postoperative 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

- Knowledge of surgical techniques, proper reduction, selection and placement of implants, and postoperative 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 postoperative 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.
- 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.
- The IPP-ON implant has not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating or migration in the MRI environment.

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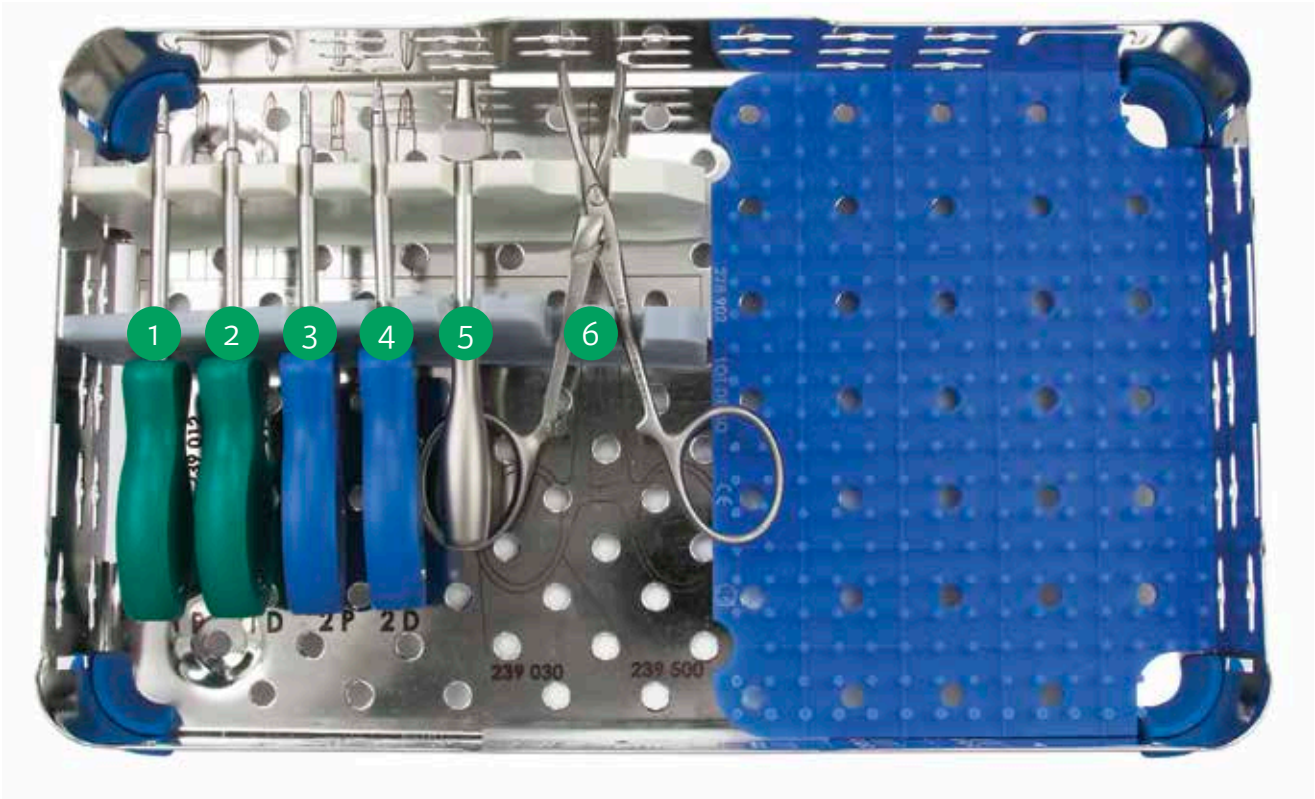
Implants

Reference	Description	Size
230 001SND	IPP-ON PIP Fusion System	1
230 002SND	IPP-ON PIP Fusion System	2

Instruments

	Reference	Description	Size
1	239 012ND	Proximal Hand Drill	1
2	239 011ND	Distal Hand Drill	1
3	239 022ND	Proximal Hand Drill	2
4	239 021ND	Distal Hand Drill	2
5	239 030ND	Handle Holder	
6	239 500ND	Clamp Holder	



Complete Set: 239 000

Reference	Description
239 001ND	Base
996 100ND	Lid
278 902ND	Mat
119 909ND	Blue Silicone Wedge

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For more information or to place an order, please contact:
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877-444-1122 USA ■ 609-936-5400 outside USA ■ 866-800-7742 fax
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