**DUAFIT® PIP**

**System**

**Ordering Info**

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Description</th>
<th>Length</th>
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<tbody>
<tr>
<td><strong>DuaFit O1-4 - 0°</strong></td>
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<tr>
<td><strong>DuaFit O2-4 - 10°</strong></td>
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**Sterile Implants Nestled in Sterile Tubes with Color-coded Configurations and Sizing**

**Peek-Optima® Implant**

- Intramedullary Design for Secure Hold During Fusion
- Features Barbed Legs for Enhanced Stabilization
- Sterile, Single-use, Recyclable Instrument Set

**2 ANGLES / 4 LENGTHS IN STERILE TUBES**

**Blister pack contains all the corresponding instruments.**

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The **DuaFit System** consists of Implants and corresponding Instruments for the arthrodesis of interphalangeal joints, including deformities of the lesser toes, such as claw, hammer and mallet toe.

This intramedullary implant features a long barbed proximal phalanx aspect and three distal blades designed to enhance stabilization.

The implants are available in 2 angles, 0° and 10° with 4 sizes each to accommodate patient specific anatomy and interphalangeal angles. The 0° implants are cannulated, providing surgeons the option to temporarily pin the corrected phalanx to the metatarsal with a guide wire.

Each DuaFit Implant comes **INDIVIDUALLY PACKAGED** and easily identifiable by style, configuration and length on the color-coded end cap.

*Streamlined, Economical Sterilization Sequence*

<table>
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<tr>
<th>INCREASED EFFICIENCY</th>
<th>LESS EFFICIENCY</th>
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<td>• SAVES TIME</td>
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<td>• MORE MONEY</td>
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For physicians and hospitals to better manage the economics, time and efficiency factors of medical devices and OR instruments, In2Bones is pleased to introduce the **DuaFit PIP Implant System**.

- OR ready implant and instrument sets
- Single use, optimized for OR efficiency
- Unique device identification labeling for traceability [unit stickers with lot#]

* Sterile delivered implants and instruments save up to an estimated $750 per case in cost and efficiency.
The DuaFit System consists of Implants and corresponding Instruments for the arthrodesis of interphalangeal joints, including deformities of the lesser toes, such as claw, hammer and mallet toe.

This intramedullary implant features a long barbed proximal phalanx aspect and three distal blades designed to enhance stabilization. The implants are available in 2 angles, 0° and 10° with 4 sizes each to accommodate patient specific anatomy and interphalangeal angles. The 0° implants are cannulated, providing surgeons the option to temporarily pin the corrected phalanx to the metatarsal with a guide wire.

Each DuaFit Implant comes INDIVIDUALLY PACKAGED and easily identifiable by style, configuration and length on the color-coded end cap.

STERILE DELIVERY TUBES

**EFFICIENT**

Sterile Delivery System

Conical **BARBED DESIGN** to enhance stabilization while securely holding adjacent phalanges during fusion.

**STERILE DELIVERY & SINGLE USE INSTRUMENT SYSTEM FOR...**

**GREATER EFFICIENCY & ECONOMY**

*Streamlined, Economical Sterilization Sequence*

**INCREASED EFFICIENCY**

- SAVES TIME
- SAVES MONEY

**LESS EFFICIENCY**

- MORE TIME
- MORE MONEY

For physicians and hospitals to better manage the economics, time and efficiency factors of medical devices and OR instruments, In2Bones is pleased to introduce the DuaFit PIP Implant System.

- OR ready implant and instrument sets
- Single use, optimized for OR efficiency
- Unique device identification labeling for traceability (unit stickers with lot#)

* Sterile delivered implants and instruments save up to an estimated $750 per case in cost and efficiency.
1 - Incision
An elliptical dorsal incision is performed at the PIP joint. Dissect soft tissue to expose the PIP joint.

2 - PIP Joint Preparation
Resect the surfaces of the proximal phalanx P1 and middle phalanx P2 to expose cancellous bone on bone contact at the fusion site at the desired angle. Avoid excessive resection.

3 - Proximal Phalanx P1
Create a pilot hole in the intramedullary canal of P1 with the DuaFit Proximal Shaper.
Note: In some cases of a narrow intramedullary canal, expansion with a 2mm Reamer may aid proper Implant insertion.

4 - Implant Size
Starting with the smallest leg of the Sizer, sequence through until a secure fit is determined. Appropriate Sizer leg will insert up to the corresponding indicators [cuts] on that leg.

5 - Middle Phalanx P2
While maintaining P2, use the Distal Shaper to create a Medial/Lateral slot in the cancellous bone.
Note: If Implant insertion proves difficult, create a second slot, centered and perpendicular to the first to improve introduction of DuaFit dorsal stem.

Note: In some cases of a narrow intramedullary canal, expansion with a 2mm Reamer may aid proper Implant insertion.

Implant Choice: Procedure Options
As noted, DuaFit implants are available in 2 angles, 0° and 10° to accommodate patient desired interphalangeal angles. Only the 0° implants are cannulated. This provides the surgeon the option to temporarily pin the corrected phalanx to the metatarsal with a K-wire. If the 0° K-wire option is preferred, skip to B7, page 6.

DUAFIT 0° with K-wire
DUAFIT 0° without K-wire or 10°

7 - Assembly: Implant and 0° Holder
Check top or side of distal end of holder axis for 0° or 10° Insert the shorter, (P2) distal end of the Implant into the Holder (tab up) up to the transition ring (junction between proximal and distal aspects).

Note: The Holder has a RAISED TAB corresponding to the dorsal aspect of the Implant and phalanx. When properly placed in the holder, the (P1) proximal end of the Implant is ready for insertion.
**DUAFIT PIP Technique**

1 - Incision
An elliptical dorsal incision is performed at the PIP joint. Dissect soft tissue to expose the PIP joint.

2 - PIP Joint Preparation
Resect the surfaces of the proximal phalanx P1 and middle phalanx P2 to expose cancellous bone on bone contact at the fusion site at the desired angle. Avoid excessive resection.

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**Note:** In some cases of a narrow intramedullary canal, expansion with a 2mm Reamer may aid proper Implant insertion.

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Starting with the smallest leg of the Sizer [1], sequence through until a secure fit is determined. Appropriate Sizer leg will insert up to the corresponding indicators [cuts] on that leg.

5 - Middle Phalanx P2
While maintaining P2, use the Distal Shaper to create a Medial/Lateral slot in the cancellous bone.
**Note:** If implant insertion proves difficult, create a second slot, centered and perpendicular to the first to improve introduction of DuaFit dorsal stem.

6 - Implant Choice: Procedure Options
As noted, DuaFit implants are available in 2 angles, 0° and 10° to accommodate patient desired interphalangeal angles. Only the 0° implants are cannulated. This provides the surgeon the option to temporarily pin the corrected phalanx to the metatarsal with a K-wire. If the 0° K-wire option is preferred, skip to B7, page 6.

7 - Assembly: Implant and 0° Holder
Check top or side at distal end of holder axis for 0° or 10°. Insert the shorter, (P2) distal end of the Implant into the Holder [tab up] up to the transition ring (junction between proximal and distal aspects).

**Note:** The Holder has a RAISED TAB corresponding to the dorsal aspect of the Implant and phalanx. When properly placed in the holder, the (P1) proximal end of the Implant is ready for insertion.
8 - Insertion into P1 Proximal Phalanx
For clear access, position the dorsal surface of P1 perpendicular to the holder. With the Implant / Holder tab up, insert the Implant to the transition ring and remove the Holder directly on axis with phalanx.

Note: Secure insertion should NOT require impacting the Implant / Holder. If the Implant remains prominent, remove and ream the insertion point with a 2.0mm drill. The Implant can then be reinserted.

9 - Introduction into P2 Middle Phalanx
Manually reduce middle phalanx over the distal aspect of the Implant and compress until the two phalanges are in flush contact and implant is fully seated.

10 - Closure
Per surgeon’s preference.

Removal
Should removal of the implant be required, expose the proximal interphalangeal joint. Distract the joint space until the distal blades of the DuaFit implant are exposed. Using surgical forceps, grasp the distal side of the implant to remove it from the middle phalanx. Then, back implant out of the proximal phalanx using surgical forceps.

The following procedure [B7-11] relates to DuaFit 0° WITH K-wire ONLY
SEE PAGE 5 FOR MORE DETAILS

B7 - K-wire Preparation of P2 Middle phalanx,
Drive the K-wire into the center of the P2. Verify the correct position with dorsal/plantar and medial/lateral fluoroscopy. With the position verified, continue to drive the K-wire distally through P2 and P3, the middle AND distal phalanx, until it exits the P3 by 4-5mm. Release the driver and reengage on the distal K-wire, pulling it thru until the proximal end protrudes 4-5mm from prepared proximal surface of the P2. Release the Driver.

This technique is not intended DuaFit 10°
Refer to page 5 for details.

B8 - Assembly Of Implant & Holder
[DuaFit 0° only, Use the Holder marked 0°]
With the Holder tab up, insert the longer, [P1] proximal end of the Implant into Holder up to the transition ring (junction between proximal and distal aspects).

Note: The Holder has a RAISED TAB corresponding to the dorsal aspect of the Implant and phalanx. When properly placed in the holder for the 0° K-wire procedure, the (P2) distal end of the Implant is ready for insertion.

B9 - Insertion into P2 Middle Phalanx
For clear access, position the dorsal surface of P2 perpendicular to proximal phalanx. Insert the Implant OVER the end if the K-wire protruding from the proximal end of the middle phalanx using the K-wire to guide insertion. Insert up to the transition ring.

B10 - Insertion into P1 Proximal Phalanx
Grasping the middle phalanx / DuaFit combined, manually reduce the proximal aspect of the DuaFit into the proximal phalanx intramedullary canal and compress until the two phalanges are in flush contact and the Implant is fully seated.

B11 - K-wire Positioning
Reengage the Driver on the distal K-wire and drive back into the proximal phalanx.
Note: Surgeon’s Discretion- K-wire may be driven back thru the metatarsal to stabilize the MTP joint and left in place during fusion / healing.

B12 - Closure
Per surgeon’s preference.

Removal
Should removal of the implant be required, expose the proximal interphalangeal joint. Distract the joint space until the distal blades of the DuaFit implant are exposed. Using surgical forceps, grasp the distal side of the implant to remove it from the middle phalanx. Then, back implant out of the proximal phalanx using surgical forceps.
8 - Insertion into P1 Proximal Phalanx
For clear access, position the dorsal surface of P1 perpendicular to the holder. With the Implant / Holder tab up, insert the Implant to the transition ring and remove the Holder directly on axis with phalanx.

Note: Secure insertion should NOT require impacting the Implant / Holder. If the Implant remains prominent, remove and ream the insertion point with a 2.0mm drill. The Implant can then be reinserted.

9 - Introduction into P2 Middle Phalanx
Manually reduce middle phalanx over the distal aspect of the Implant and compress until the two phalanges are in flush contact and implant is fully seated.

10 - Closure
Per surgeon preference.

Removal
Should removal of the implant be required, expose the proximal interphalangeal joint. Distract the joint space until the distal blades of the DuaFit implant are exposed. Using surgical forceps, grasp the distal side of the implant to remove it from the middle phalanx. Then, back implant out of the proximal phalanx using surgical forceps.

The following procedure [B7-11] relates to DuaFit 0° WITH K-wire ONLY
SEE PAGE 5 FOR MORE DETAILS

B7 - K-wire Preparation of P2 Middle phalanx
Drive the K-wire into the center of the P2. Verify the correct position with dorsal/plantar and medial/lateral fluoroscopy. With the position verified, continue to drive the K-wire distally through P2 and P3, the middle AND distal phalanx, until it exits the P3 by 4-5mm. Release the driver and reengage on the distal K-wire, pulling it thru until the proximal end protrudes 4.5mm from prepared proximal surface of the P2. Release the Driver.

This technique is not intended DuaFit 10°
Refer to page 5 for details.

B8 - Assembly Of Implant & Holder
[DuaFit 0° only, Use the Holder marked 0°]
With the Holder tab up, insert the larger, [P1] proximal end of the Implant into Holder up to the transition ring (junction between proximal and distal aspects).

Note: The Holder has a RAISED TAB corresponding to the dorsal aspect of the Implant and phalanx. When properly placed in the holder for the 0° K-wire procedure, the (P2) distal end of the Implant is ready for insertion.

B9 - Insertion into P2 Middle Phalanx
For clear access, position the dorsal surface of P2 perpendicular to proximal phalanx. Insert the Implant OVER the end of the K-wire protruding from the proximal end of the middle phalanx using the K-wire to guide insertion. Insert up to the transition ring.

B10 - Insertion into P1 Proximal Phalanx
Grasping the middle phalanx / DuaFit combined, manually reduce the proximal aspect of the DuaFit into the proximal phalanx intramedullary canal and compress until the two phalanges are in flush contact and the Implant is fully seated.

B11 - K-wire Positioning
Re-engage the Driver on the distal K-wire and drive back into the proximal phalanx.

Note: Surgeons Discretion - K-wire may be driven back thru the metatarsal to stabilize the MTP joint and left in place during fusion / healing.

B12 - Closure
Per surgeon preference.

Removal
Should removal of the implant be required, expose the proximal interphalangeal joint. Distract the joint space until the distal blades of the DuaFit implant are exposed. Using surgical forceps, grasp the distal side of the implant to remove it from the middle phalanx. Then, back implant out of the proximal phalanx using surgical forceps.

DuaFit™ Pip System
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ordering info

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DuaFit PIP System

2 Configurations

<table>
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<tr>
<th>Configuration</th>
<th>DuaFit O1 - 0°</th>
<th>DuaFit O2 - 10°</th>
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<tbody>
<tr>
<td>DuaFit O1.4</td>
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</tr>
<tr>
<td>DuaFit O2.4</td>
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DuaFit Single Use Instruments Set

- Blister pack contains all the corresponding instruments.

- Universal Driver Handle
  - 0° specific
  - 10° specific

- P1 Canal Shaper
  - 0° specific
  - 10° specific

- P2 Canal Shaper
  - 0° specific
  - 10° specific

- Sizer
  - 0° specific
  - 10° specific

- K-Wire: 10 x 100mm dual trocar ends

DUAFIT "STRAIGHT"

Sterile Implants Nested in Sterile Tubes with Color-coded Configurations and Sizes:

<table>
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<tr>
<th>DuaFit O1-4</th>
<th>DuaFit O2-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>0° - Straight, Sterile - PEEK</td>
<td>10° - Angled, Sterile - PEEK</td>
</tr>
<tr>
<td>A60SP001 - DuaFit 0° - Straight - 11mm</td>
<td>A60SP102 - DuaFit 10° - Angled - 14mm</td>
</tr>
<tr>
<td>A60SP002 - DuaFit 0° - Straight - 14mm</td>
<td>A60SP103 - DuaFit 10° - Angled - 17mm</td>
</tr>
<tr>
<td>A60SP003 - DuaFit 0° - Straight - 17mm</td>
<td>A60SP104 - DuaFit 10° - Angled - 20mm</td>
</tr>
</tbody>
</table>

DuaFit Sterile Disposable Instrument Set (See below)

- P/N A06-10401
- 2 ANGLES / 4 LENGTHS IN STERILE TUBES
- Sterile Disposable Instrument Set = P/N A06-10401
- Sterile Implants Nested in Sterile Tubes with Color-coded Configurations and Sizes
- Blister pack contains all the corresponding instruments.

DUAFIT "ANGLED - 10°"

- Push lever and extract Driver/axis
- Radio Transparent PEEK-OPTIMA®
- Radio opaque K-Wire: 10 x 100mm dual trocar ends
- Quick Release Tab
- Color-coded & numeric configuration

- Single Use Instruments Set
- P/N A06-10401
- 2 ANGLES / 4 LENGTHS IN STERILE TUBES

- Intramedullary Design for Secure Hold During Fusion
- Features Barbed Legs for Enhanced Stabilization
- Sterile, Single-use, Recyclable Instrument Set

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