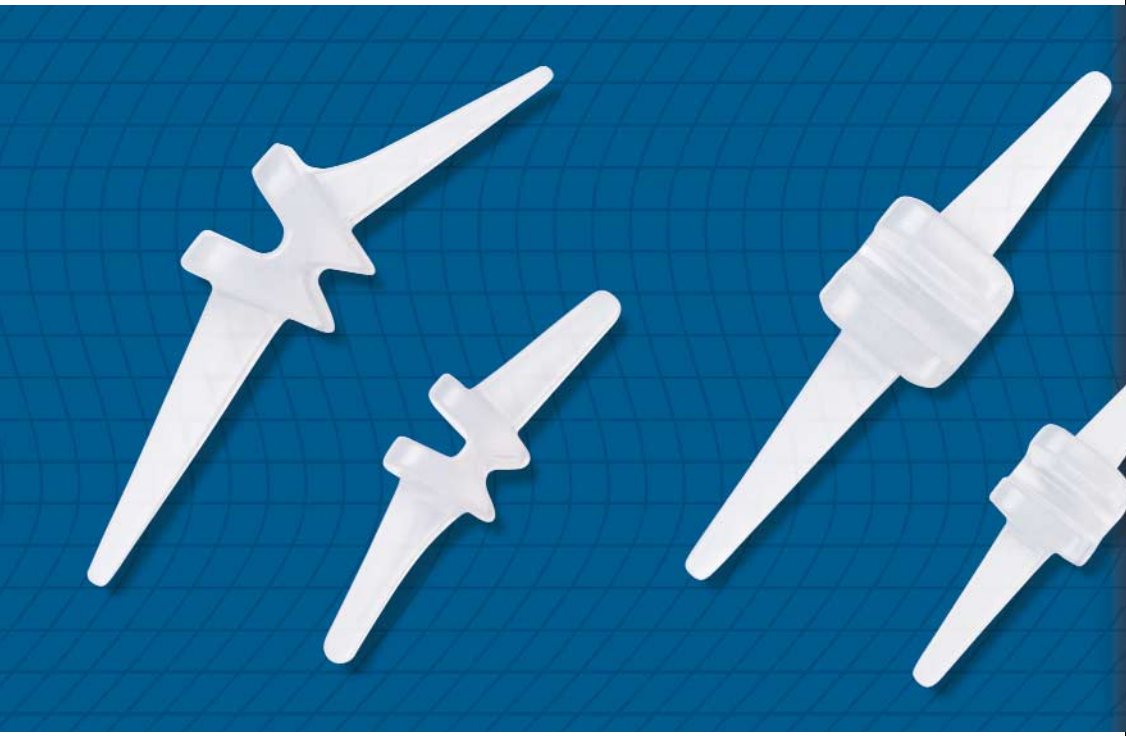
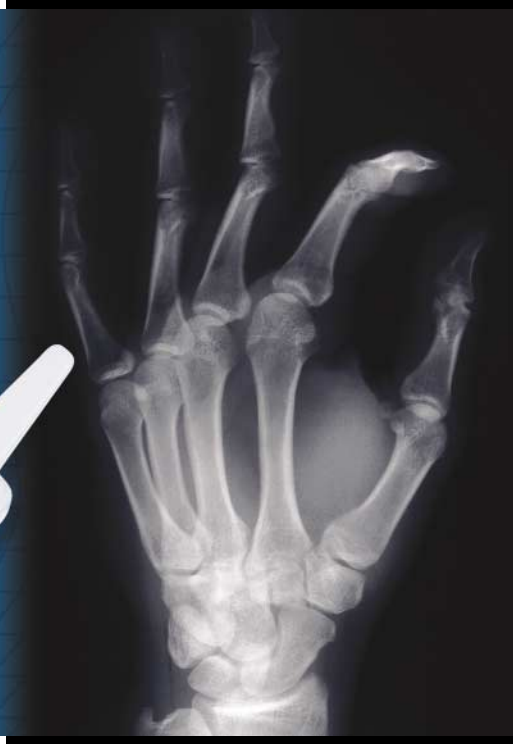
DESIGN RATIONALE AND SURGICAL TECHNIQUE

NeuFlex™

MCP/PIP JOINT IMPLANTS





ASSISTS IN RESTORING FUNCTION AND QUALITY OF LIFE

DePuy
a Johnson & Johnson company

MCP PIP *DESIGN RATIONALE*

The NeuFlex™ MCP and PIP Finger Joint Implant Systems feature implants made from silicone. The systems incorporate the anatomically shaped implant, ergonomically designed instruments and an enhanced skin incision procedure. These innovative systems offer the medical community superior technology when compared with competitive designs. The NeuFlex MCP and PIP joint systems assist in restoring function and quality of life to patients with rheumatoid, degenerative or traumatic arthritis.

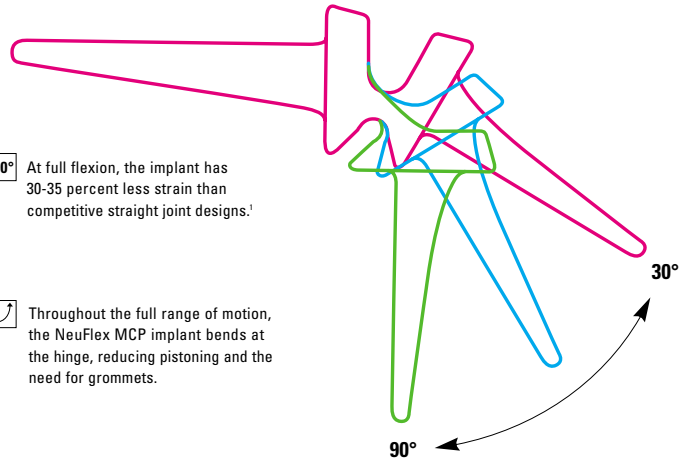
NeuFlex™ MCP PIP anatomic implants feature:

- The **preformed, anatomically neutral angle** (30 degree in the MCP, 15 degree in the PIP), approximates the relaxed position of the human hand at optimal flexor/extensor tendon resting tone.
- In the MCP design, the maximum bending action needed is 60 degrees to achieve full flexion, versus 90 degrees for a straight-stemmed, hinged silicone implant. This **reduces strain by 30-35 percent**, promotes **longer fatigue life** and the possibility to achieve **greater finger flexion** and thus, function.[1]
- The PIP design also allows for 15 degrees of added extension needed to replicate normal human hand function using minimal patient effort.
- Implant geometry provides for flexion in the hinge region, which greatly reduces pistoning and abrasion, and eliminates the need for grommets.
- The anatomic shape provides better fit and fill within the canals and helps decrease the likelihood of dislocation.
- Gas plasma sterilization provides an environmentally safe process and does not alter the implant's material properties.
- The hinge section for the PIP design has been carefully engineered to further reduce material strain at 90-degree flexion.

30° The NeuFlex MCP implant is designed with a neutral angle to approximate the joint at rest while still allowing extension.

90° At full flexion, the implant has 30-35 percent less strain than competitive straight joint designs.[1]

Throughout the full range of motion, the NeuFlex MCP implant bends at the hinge, reducing pistoning and the need for grommets.



NeuFlex MCP Versus Competition – Strain Versus Angle[1]

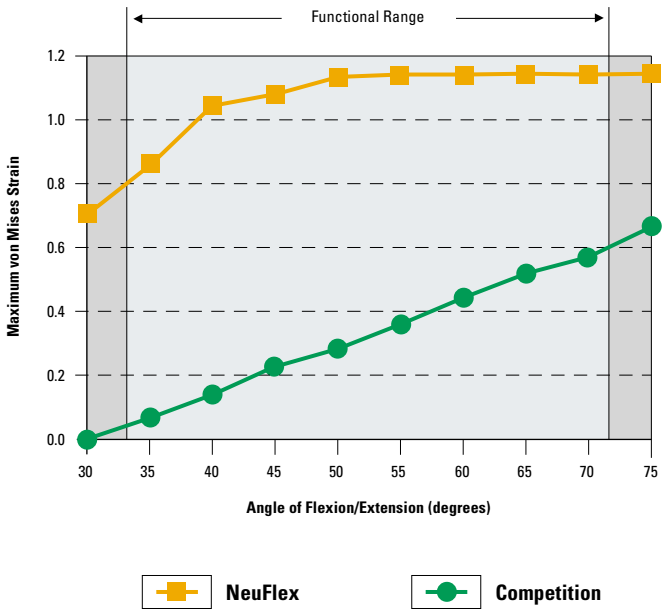


Chart demonstrates the functional range of motion where less strain occurs during daily activities on the NeuFlex MCP than its competition.

MCP SURGICAL TECHNIQUE

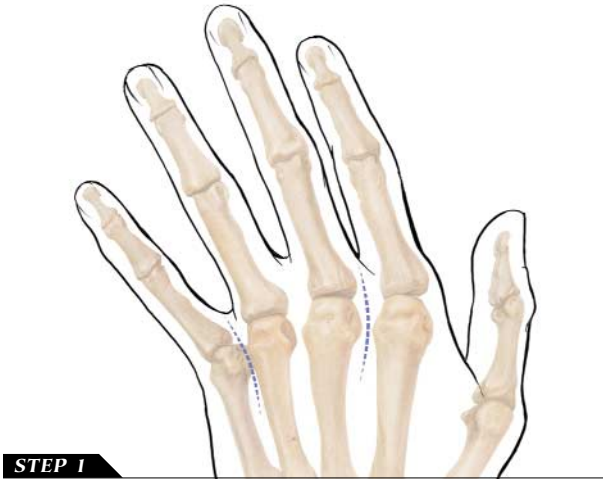
Expose the metacarpal joint using bilongitudinal skin incisions or a single transverse incision across the metacarpal heads.

Note: *This technique will focus on the bilongitudinal skin incision.*

Summary provided by designing surgeon Arnold-Peter C. Weiss, MD, Providence, R.I.

STEP 1

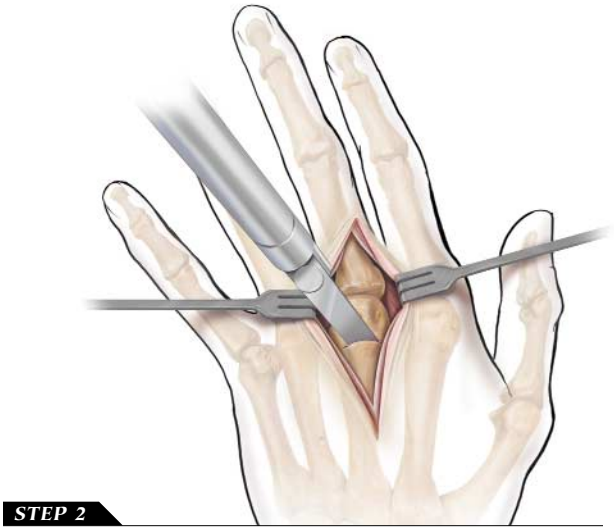
Make one 5 cm longitudinal incision between the index and middle finger metacarpal heads and one between the ring and small finger metacarpal heads. This incision will allow access to two adjacent MCP joints. Perform subcutaneous dissection to the extensor hood. Incise the ulnar sagittal band and extensor hood longitudinally, with the entire extensor tendon reflected radially. Next, excise inflammatory synovium with a rongeur.



STEP 1

STEP 2

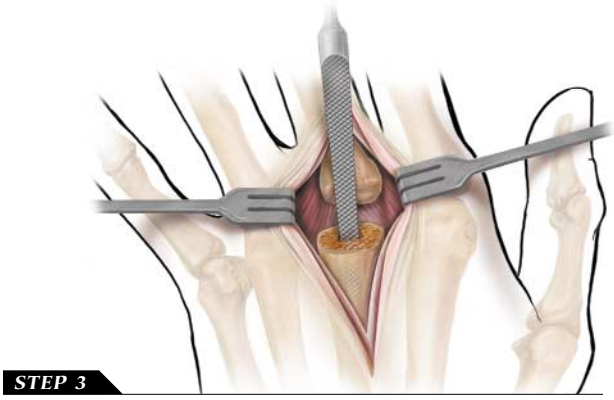
Resect the metacarpal head at the distal end of the metacarpal metaphyseal flare, using a micro-oscillating saw in a plane perpendicular to the long axis of the metacarpal shaft. Generally, resection of the base of the proximal phalanx is not required. Using rongeurs, remove any sharp osteophytes or spurs from the joint.



STEP 2

STEP 3

To establish starting alignment for subsequent broaching, introduce the rasp/awl combination instrument in the metacarpal shaft and proximal phalanx.

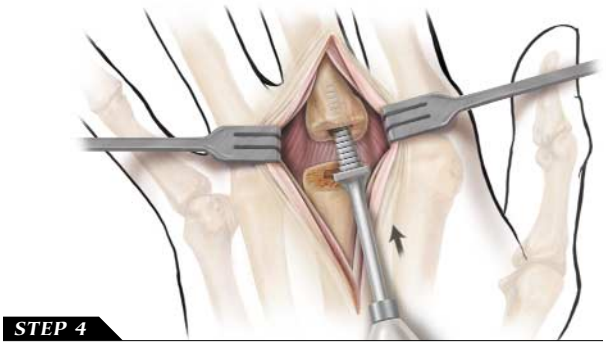


STEP 3

MCP SURGICAL TECHNIQUE CONT.

STEP 4

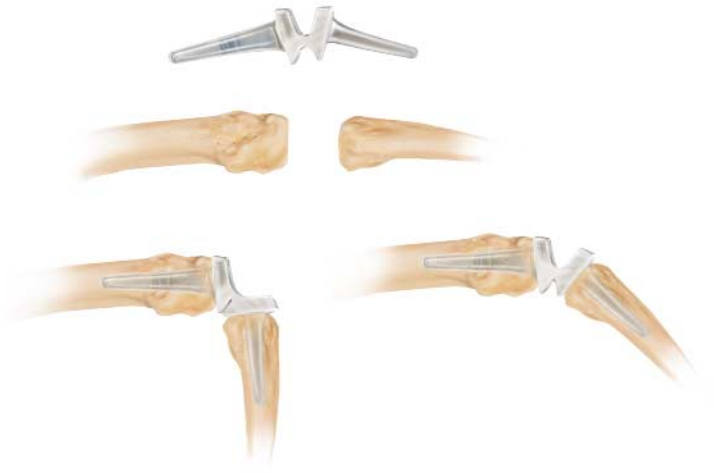
Beginning with the smallest broach, prepare the metacarpal canal to the largest size acceptable to allow full seating of the broach to the stop flange. To avoid rotation during broaching, use an advancing-retracting rasping method.



STEP 4

STEP 5

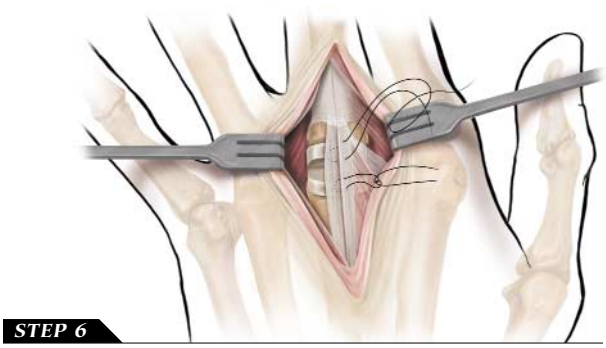
Use the trial implant corresponding to the smaller of the fully seated and maximized broaches (either proximal or distal) with smooth forceps. Insert the larger metacarpal stem first. Follow by inserting the distal stem with the finger flexed to aid with final seating. Check the range of motion and alignment of the MCP arthroplasty. Insert the final implant after size evaluation.



STEP 5

STEP 6

Use one or two horizontal mattress sutures tensioned to have the extensor tendon positioned directly over the midline of the dorsal portion of the metacarpophalangeal joint. Imbricate the radial hood and sagittal band. Range the joint again to ensure there is no subluxation of the extensor tendon from 0 to 90 degrees of flexion. Irrigate the wounds with the skin closed over a thin silicone drain.



STEP 6

POSTOPERATIVE CARE

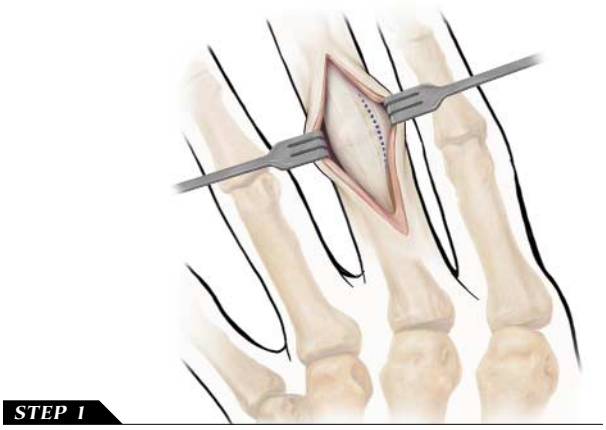
After all four MCP arthroplasties have been performed, place a bulky-fluff dressing with a volar splint, maintaining the four fingers in approximate longitudinal alignment and full extension. Leave the splint in place for five to eight days, prior to beginning early therapeutic range of motion and splinting.

PIP SURGICAL TECHNIQUE

Summary provided by designing surgeon Arnold-Peter C. Weiss, MD, Providence, R.I.

STEP 1

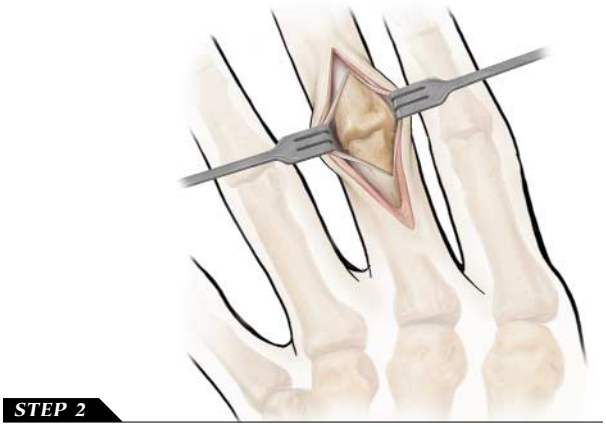
Make a gradual curving dorsal incision over the PIP joint. Carry dissection down to the extensor tendon mechanism. Gently elevate skin flaps by careful dissection to expose an appropriate portion of the extensor tendon mechanism. Make an incision between the central tendon of the extensor tendon mechanism and the lateral band on one side of the digit using a #15 blade. Occasionally, an incision needs to be made between the central tendon and the lateral band on the opposite side of the digit. However, this is not always the case.



STEP 1

STEP 2

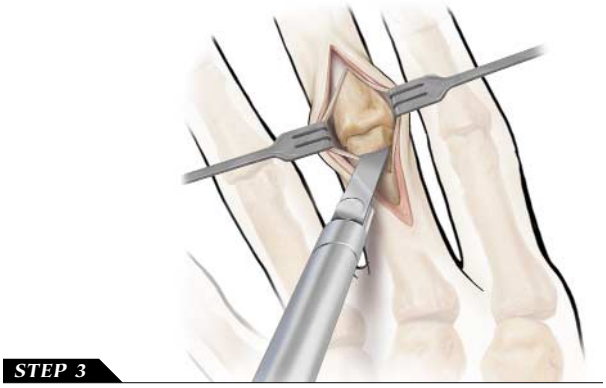
Incise the dorsal capsule longitudinally to expose the dorsal PIP joint. Some recession of the dorsal portion of the collateral ligaments may be required to allow appropriate exposure of the proximal interphalangeal joint.



STEP 2

STEP 3

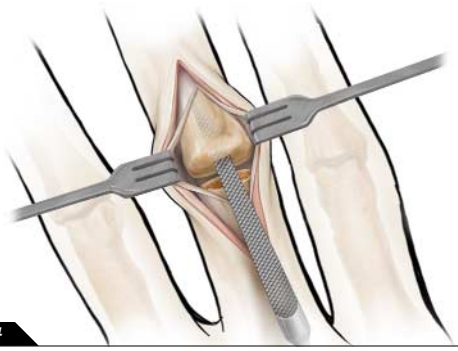
While protecting the central tendon using retractors, use a micro-oscillating saw to resect the proximal phalanx head at the metaphyseal flare. Use a rongeur to remove spurs from the base of the middle phalanx.



STEP 3

STEP 4

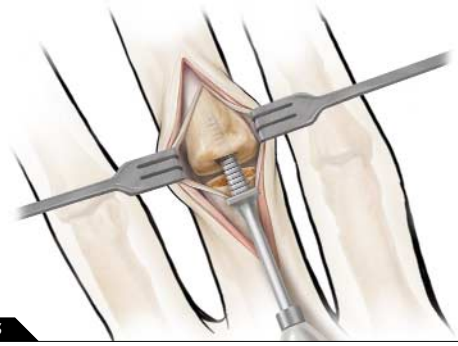
Use the rasp/awl combination instrument to begin opening canals in both the proximal and middle phalanges.



STEP 4

STEP 5

Use sequentially sized broaches to form both the middle and proximal phalanx up to a maximum size that will seat the broach completely.

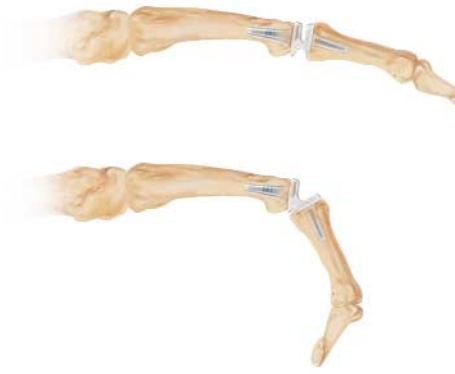


STEP 5

STEP 6

Use trial implants to size and ensure appropriate stability after implantation. The trial implant should sit flush against the middle and proximal phalanx and be relatively stable.

Occasionally, in order to gain enough exposure in difficult cases, the collateral ligament on one side needs to be released from the proximal phalanx to allow exposure. If this is required, repair the collateral ligament using monofilament nonabsorbable #4-0 sutures through drill holes in the proximal phalanx after the implant has been placed. If necessary, repair the capsule and the extensor mechanism, with nonabsorbable #4-0 multifilament sutures. Place a drain and close the skin with a conforming dressing, maintaining the PIP joint in a very slight flexion of 10 to 20 degrees.



STEP 6

POSTOPERATIVE CARE

Guarded active flexion/extension exercises can commence several days after the procedure, ensuring that any repaired collateral ligaments are protected from deviating forces for at least four to six weeks. Alternatively, the finger can be splinted in a resting position for up to three to four weeks after which range of motion exercises can begin.

MCP Implants	
Cat. No.	**Size**
1234-00-000	0
1234-10-000	10
1234-20-000	20
1234-30-000	30
1234-40-000	40
1234-50-000	50
1234-60-000	60

MCP Instruments				
Cat. No.	**Size/Color**		**Cat. No.**	**Size/Type**
Trial:			**Broach:**	
2634-00-000	0	Pink	2634-01-000	0 Proximal
			2634-02-000	0 Distal
2634-10-000	10	Yellow	2634-11-000	10 Proximal
			2634-12-000	10 Distal
2634-20-000	20	Orange	2634-21-000	20 Proximal
			2634-22-000	20 Distal
2634-30-000	30	Red	2634-31-000	30 Proximal
			2634-32-000	30 Distal
2634-40-000	40	Blue	2634-41-000	40 Proximal
			2634-42-000	40 Distal
2634-50-000	50	Green	2634-51-000	50 Proximal
			2634-52-000	50 Distal
2634-60-000	60	Black	2634-61-000	60 Proximal
			2634-62-000	60 Distal
Instruments:				
2634-90-000	Rasp/Awl			
2634-93-000	Instrument Tray			

PIP Implants	
Cat. No.	**Size**
1233-10-000	1
1233-20-000	2
1233-30-000	3
1233-40-000	4
1233-50-000	5

PIP Instruments

	Cat. No.	Size/Color	Cat. No.	Size/Type
	Trial:		**Broach:**	
■	2633-10-000	1 Blue	2634-11-000	10 Proximal
			2634-12-000	10 Distal
■	2633-20-000	2 Teal	2634-21-000	20 Proximal
			2634-22-000	20 Distal
■	2633-30-000	3 Yellow	2634-31-000	30 Proximal
			2634-32-000	30 Distal
■	2633-40-000	4 Purple	2634-41-000	40 Proximal
			2634-42-000	40 Distal
■	2633-50-000	5 Olive	2634-51-000	50 Proximal
			2634-52-000	50 Distal

Instruments:

2634-90-000	Rasp/Awl
2633-93-000	Instrument Tray

INSTRUMENTS

The NeuFlex MCP and PIP Finger Joint Implant Systems offer proven and efficient instrumentation, which provide the surgical staff with easy-to-use, color-coded proximal and distal broaches and corresponding trials.

The NeuFlex instruments feature:

- Ergonomically designed handles for surgical ease of use.
- Color-coded proximal and distal broaches and trials for quick identification and reduced OR time.

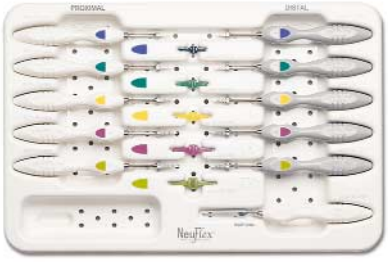
- Dual action tooth pattern with a stop flange on the broaches, designed to match the size of the corresponding colored trials and implant stems, allows for cutting and removal of bone in one easy step.
- A complete range of trial sizes from 0-60 (MCP) and 1-5 (PIP) to comply with every patient need.

MCP

PIP

- Rasp/awl combination tool is designed to save OR time and provide surgical ease of use.

- A single, lightweight instrument sterilization case houses the instruments and is color-coded for ease of use. A utility bin area is included to house ancillary instruments.



ESSENTIAL PRODUCT INFORMATION

Important: This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications

The NeuFlex MCP and PIP Finger Joint Implant Systems are indicated for replacement of the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

Contraindications

The following conditions are contraindications for use of a MCP or PIP finger prostheses.

1. Active local or systemic infection.
2. Destruction of the metacarpal or phalanx, or poor bone quality which prevents adequate fixation of the implant.
3. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected finger.
4. Growing patients with open epiphyses.
5. Patients with high activity levels.
6. Patients unwilling or unable to comply with the physician's instructions.

WARNINGS AND PRECAUTIONS: The following conditions tend to adversely affect finger replacement implants: excessive activity, deformity, inadequate implant sizing or malpositioning and insufficient support.

ADVERSE EVENTS: The following are the most frequent adverse events after finger joint replacement: infection, implant failure, wear particles, which may exacerbate existing conditions, and tissue or immunological reactions to silicone.

REFERENCE
1. Data on file at DePuy Orthopaedics, Inc.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

US Patent 5,824,095. Other US and foreign patents pending.

For more information about the NeuFlex MCP/PIP Finger Joint Implant Systems, visit our web site at **www.jnjgateway.com.**

Contact your local DePuy sales representative for information about DePuy shoulder products, including the Global™ Total Shoulder System, Global Advantage® Shoulder, Global Fx Shoulder and Global Rehabilitation Kit. DePuy also offers an entire range of implants for both upper and lower extremity joint replacement and a complete line of bone cement products.

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