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SURGICAL
TECHNIQUE

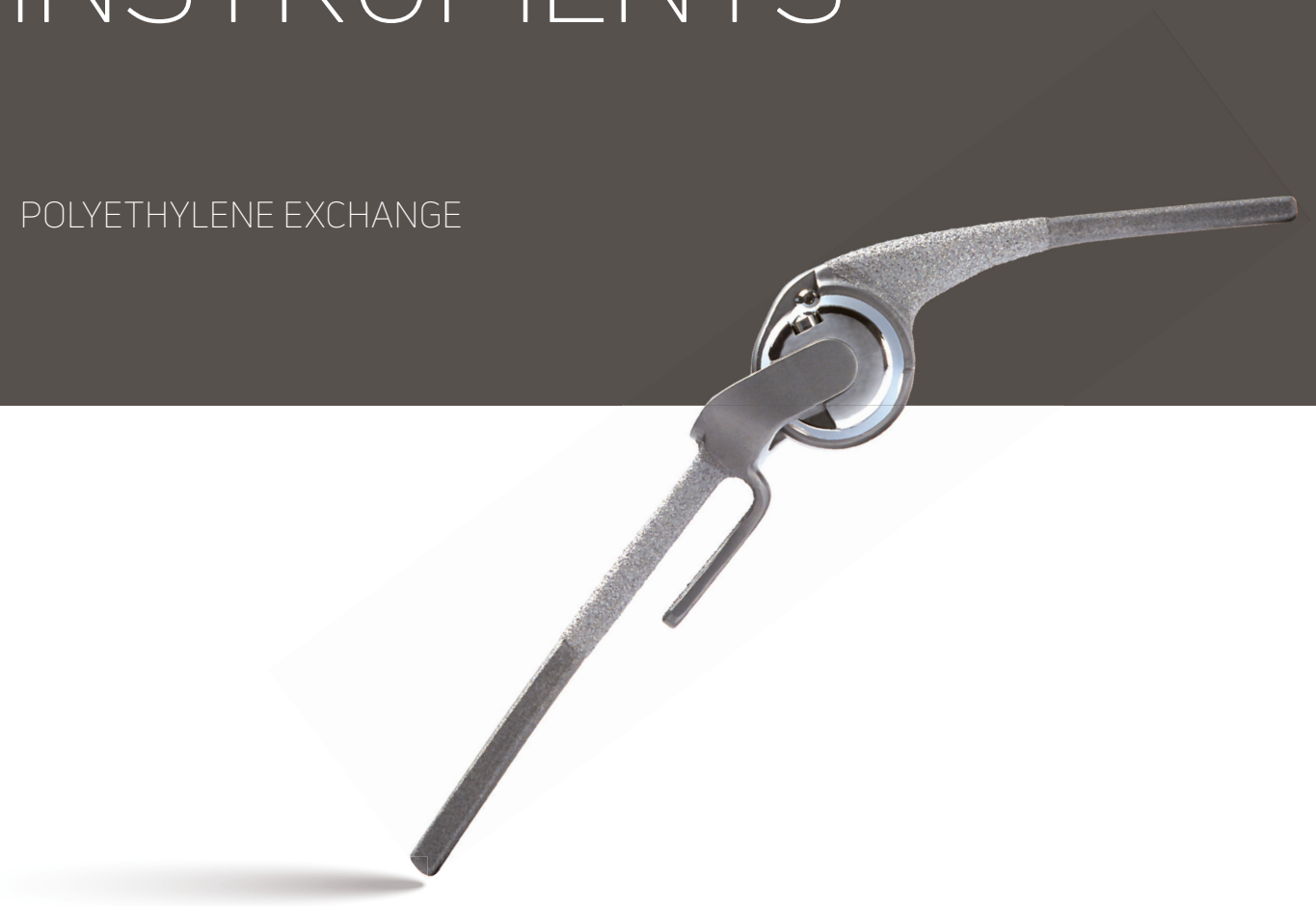
enovis

DISCOVERY ELBOW SYSTEM

a LimaCorporate family product

SURGICAL INSTRUMENTS

POLYETHYLENE EXCHANGE



DISCOVERY ELBOW SYSTEM POLYETHYLENE EXCHANGE
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Limacorporate S.p.A. is a manufacturer of prosthetic implants and as such dœs not perform medical procedures. This documentation concerning surgical techniques, which provides surgeons with general guidelines for implanting the Discovery Elbow System Polyethylene Exchange, was developed with the advice of a team of surgical experts. All decisions as to the type of surgery and most suitable technique are obviously the responsibility of the health care professional. Surgeons must make their own decisions as to the adequacy of each planned implant technique based on their training, experience and the clinical condition of the patient. For further information about our products, please visit our web site at www.limacorporate.com

DISCOVERY ELBOW POLYETHYLENE EXCHANGE

Indications, contraindications and risk factors

INDICATIONS

Discovery Elbow System is a semi-constrained elbow replacement system intended for primary and revision joint arthroplasty. Discovery Elbow System is indicated for patients with:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- revision where other devices or treatments have failed;
- correction of functional deformity;
- treatment of acute or chronic fractures with humeral epicondyle involvement, which are unmanageable using other treatment methods;

All Discovery Elbow components are intended for use with bone cement.

CONTRAINDICATIONS

Absolute contraindications include:

- infection;
- sepsis;
- osteomyelitis.

Relative contraindications include:

- uncooperative patient or patient with neurologic disorders who is incapable of following directions;
- osteoporosis;
- metabolic disorders which may impair bone formation;
- osteomalacia;
- distant foci of infections which may spread to the implant site;
- rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.

RISK FACTORS

The following risk factors may result in poor results with this prosthesis:

- overweight*;
- strenuous physical activities (active sports, heavy physical work);
- incorrect implant positioning;
- muscle deficiencies;
- refusal to modify postoperative physical activities;
- patient history of infections;
- systemic diseases and metabolic disorders;
- drug therapies that adversely affect bone quality, healing, or resistance to infection;
- patient's resistance to disease generally weakened (HIV, tumour, infections);
- severe deformity leading to impaired anchorage or improper positioning of implants;
- use our combinations with products, prosthesis or instruments of another manufacturer;
- patient smoking.

* *According to the definition of the World Health Organization (WHO), Body Mass Index (BMI) greater than or equal to 25 Kg/m^2.*

COMBINATIONS ALLOWED / NOT ALLOWED

- X-small humeral components should only be used with x-small ulnar components.
- X-small humeral condyles should only be used with x-small humeral components.
- X-small bearing kits should only be used with x-small ulnar components.

Limacorporate specialized technical staff is available to provide advice regarding pre-operative planning, the surgical technique, and product and instrumentation assistance both prior to and during surgery.

figure 1

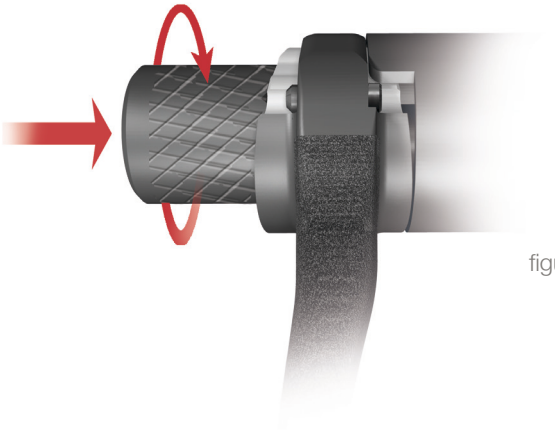

figure 2

PREOPERATIVE PLANNING

Place two ulna bearing kits in a freezer for a minimum of three hours. Freezing causes the bearing to constrict, making it easier to insert into the ulna ring. The temperature should be between -13° F and 14° F (-25° C and -10° C). A lower freezer temperature will increase the handling time of the bearing. Do not remove the bearing from the freezer until ready for assembly, as it will begin to expand immediately and reach full expansion within two minutes of removal. The second bearing kit should remain in the freezer as reserve.

BEARING REMOVAL

Insert the threaded end of the bearing removal tool through the center hole of the ulna component. Push the T-handle toward the ulna component as far as possible, turning the T-handle to allow the threaded shaft to pass through the bearing if necessary. The ledge of the ulna component should fit into the recess on the body of the bearing removal tool (Figure 1). With the jagged end toward the polyethylene, tighten the end cap onto the bearing removal tool (Figure 2).

This brochure is presented to demonstrate the surgical technique of Hill Hastings II, Limacorporate, as the manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

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Bearing Removal \New Bearing Insertion

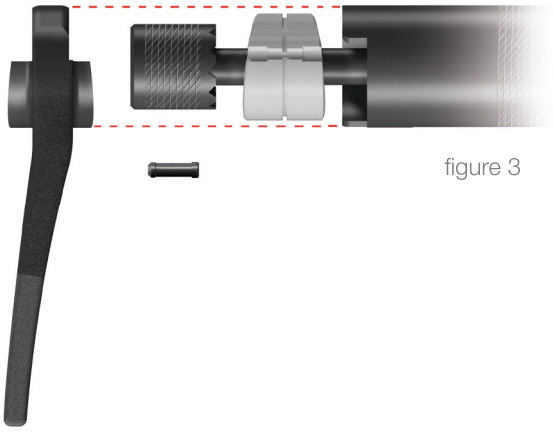


figure 3

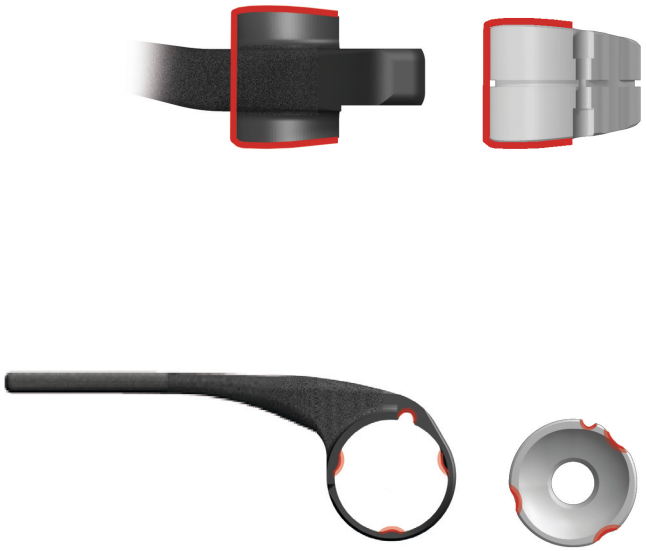


figure 4

While holding the body of the removal tool, rotate the T-handle clockwise. The polyethylene will be pulled from within the ulna component onto the threaded shaft of the removal tool. Continue rotating until the polyethylene is removed from the ulna stem and the locking pin falls free (Figure 3). Discard the pin and polyethylene; irrigate and remove any small polyethylene particles.

NEW BEARING INSERTION

Remove one ulna bearing revision kit from the freezer. The widest portion of the bearing should face toward the widest portion of the ulna ring (Figure 4). Locate the four notches on the outer edge of the bearing and align the cylindrical notch (pin groove) posteriorly.

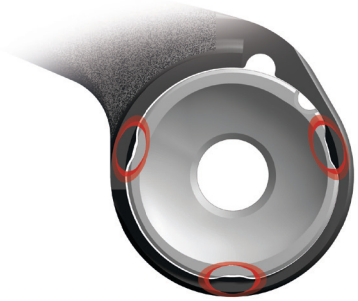


Figure 5

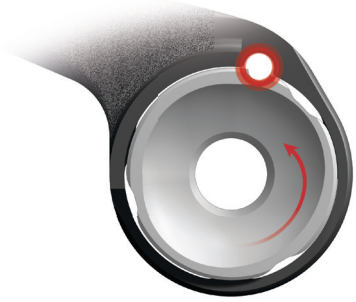


Figure 6

Align the three shallow notches in the bearing with the three tabs inside the ulna stem ring (Figure 5). Insert the bearing into the middle of the stem ring by pushing it until the bearing freely spins/rotates. Rotate the bearing until the cylindrical notch (pin groove) aligns with the pin groove of the ulna stem (Figure 6).

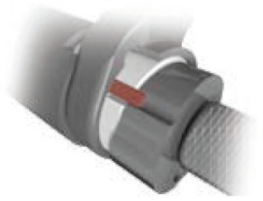


Figure 7

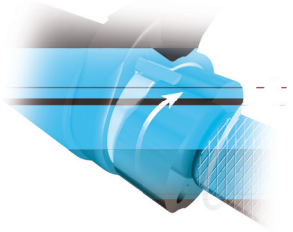


Figure 8

OPTIONAL BEARING INSERTION METHOD

The bearing rotation tool may be used to rotate the bearing if it does not spin freely when inserted into the ulna ring. To use, insert the tool from the medial side of the bearing, allowing the long metal tab to slide into the groove on the bearing reserved for the locking pin (Figure 7).

Rotate the bearing until the cylindrical notch in the bearing is aligned with the pin groove of the ulna stem (Figure 8).

DISCOVERY ELBOW SYSTEM POLYETHYLENE EXCHANGE
Pin Insertion

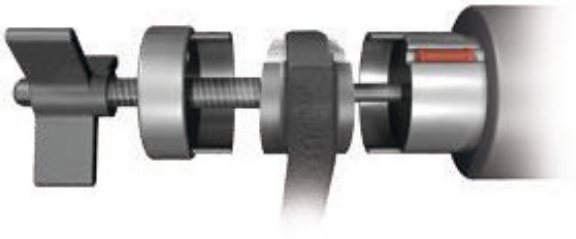


Figure 9

Figure 11

Figure 10

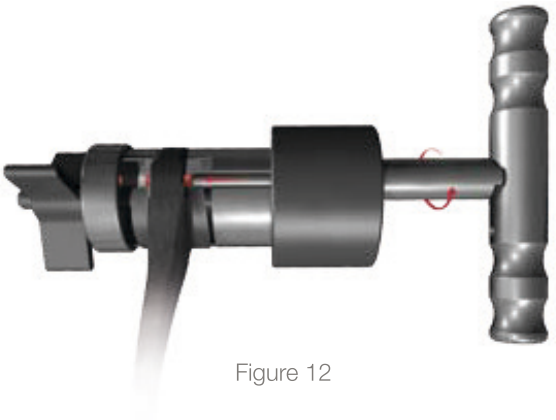


Figure 12

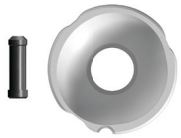
PIN INSERTION

Insert the ulna pin inserter body through the bearing from the medial side until the ledge of the ulna component fits into the recess on the body of the pin inserter. Secure the ulna component into place using the lock body and lock nut. The push rod should be backed out enough to place the locking pin into the small canal (Figure 9). The tapered end of the pin should be facing toward the ulna component. (Figure 10)

The hole in the lock body, groove in the ulna component and pin should be aligned (Figure 11). Attach the T-handle and turn clockwise to drive the pin into the ulna component (Figure 12). Ensure the pin dœs not become dislodged during insertion. Once the pin is fully inserted into the ulna component, bearing exchange is complete.

DISCOVERY ELBOW POLYETHYLENE EXCHANGE

Implants



PART NUMBER	DESCRIPTION	SIZE
114800*	**Discovery** Ulna Bearing Revision Kit	
114801*	**Discovery** XS Ulna Bearing Revision Kit	

*Contains one polyethylene bearing and locking pin

**Available from loaners

DISCOVERY ELBOW SYSTEM POLYETHYLENE EXCHANGE
Instruments

Discovery Revision Kit 9014.60.000

PART NUMBER	DESCRIPTION	SIZE
414950	Bearing Removal Tool	
414951	Bearing Ulna Pin Inserter	
414952	Bearing Rotation Tool	
414892	T-Handle	
414922	2.0/2.7mm Screwdriver Handle	
414923	2.4mm X-Lock STD Screwdriver	
414926	Hexalobular Screwdriver	
9014.60.9D0	Revision Kit Case	

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Prescription use only: sold only on or by order of a physician.

This technique is valid only for the European Economic Area, Switzerland and Japan.

This publication is not intended for distribution in the U.S.