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I. Understanding Shoulder Replacement

A total shoulder replacement has been recommended for the treatment of your shoulder problem. This operation is being performed as part of a research trial since you have either Osteoarthritis, Rheumatoid Arthritis, Traumatic Arthritis or Avascular Necrosis. These conditions are discussed in this booklet as well as in the Informed Consent for the research trial. The purpose of this booklet is to provide you more information about each of the devices that you may receive during the total shoulder replacement. If you have questions specifically about the shoulder surgery or after reading this handout, please ask your surgeon.

The Normal Shoulder

The shoulder joint is very complex and involves three bones and more than one joint. These bones are the clavicle (collar bone), the scapula (shoulder blade) and the humerus (upper arm bone). Numerous muscles, ligaments and tendons surround the joint (Figure 1). The upper end of the arm bone (humerus) and the outside edge of the scapula bone (glenoid) form a “ball-and-socket joint”. This joint is remarkable because it typically allows greater range of motion than any other joint in your body (Figures 2 and 3).
Why Do You Need a Total Shoulder Replacement?

Total shoulder replacement surgery is a result of degeneration of the ball-and-socket joint. When the smooth surfaces (cartilage) of the ball-and-socket (cartilage) become rough, they rub against each other rather than glide. This rubbing causes pain, stiffness and swelling. Patients that decide to have a total shoulder replacement surgery as part of this research trial will have to have had continued shoulder pain despite at least six months of treatments (e.g.: anti-inflammatory, physical therapy and steroid injections). Additionally, patients will have to have had pain and stiffness that interfere with their activities of daily living.

The total shoulder replacement is performed to help alleviate pain and improve range of motion of your shoulder joint, which may also improve your function and quality of life.

Reasons For A Total Shoulder Replacement In This Research Trial

- Severe degenerative joint disease (Osteoarthritis) – the cartilage has worn away resulting in bone to bone contact (Figure 4)
- Inflammatory/Rheumatoid Arthritis – cartilage is destroyed by inflammation, common in these joint processes
- Avascular Necrosis – bone death, loss of blood supply to the humeral head (ball)

Figure 4

[Diagram showing normal and degenerated shoulder joints]
Univers II Shoulder Replacement

The essential part of the surgery is to remove the damaged area and replace it with a shoulder prosthesis (artificial joint). To access the shoulder joint an incision is made on the front of your shoulder. After exposing the shoulder joint, the damaged ends of the bone (humerus and glenoid) are removed. The bone is prepared for the replacement with the artificial joint.

The artificial joint is made of metal, usually a titanium or a cobalt-chrome alloy. The stem is placed inside the humerus bone. Bone cement may be used to secure the stem in the humerus.

The glenoid component has two options: the keeled glenoid and the pegged glenoid. Both are made of a special plastic (polyethylene). The glenoid is cemented into place. The glenoid used is determined by surgeon preference.

After the components are in place, the shoulder joint is checked to make sure it is stable and has the potential for good motion after rehabilitation.
Eclipse Shoulder Replacement

For an Eclipse shoulder replacement procedure, much of the surgery is the same. However, the components of the Eclipse shoulder replacement are different. The Eclipse humeral implant is fixed using a hollow screw system.

This device is not yet cleared by the FDA for sale in the U.S.
II. Preparing for Your Joint Replacement Surgery

Now That You Are Scheduled For Surgery
The following information will be discussed with you in your surgeon’s office.

• Preoperative teaching about the surgical procedure
• Surgical risks
• Preparation for surgery
• Discharge planning
• Home preparation for after surgery
• Information about required tests

Risks, Side Effects and Discomforts
Some risks come with every operation and they differ for each person depending on the person’s age, health, and the type of surgery performed. Potential risks include:

1. Infections can occur but your doctor and the hospital staff will take care to prevent infections. You must contact your doctor if you notice signs of infection (increased redness, swelling at the wound site and fever).

2. Allergies and other reactions to device materials can occur. Your doctor and the research team will ask you about previous reactions and if they think you are at risk for an allergic reaction. You must contact your doctor or medical staff if you notice signs of an allergic reaction (itching, hives, swelling, difficulty breathing or swallowing).

3. Temporary or permanent nerve damage is a risk associated with any surgical procedure. Your doctor is a qualified orthopaedic surgeon and he/she has received specific training in the use of this investigational device to minimize the risks of nerve damage associated with this procedure. You must contact your doctor if you experience numbness or lack of sensation in your arm following surgery.
4. Bruising (hematoma) is a risk associated with any surgical procedure. Your doctor and research team will review your record to help determine if you are at risk for extensive bruising.

5. Cardiovascular complications, including venous thrombosis, pulmonary embolism, and heart attack (cardiac arrest) are risks associated with any surgical procedure. Your doctor and the research team will review your record to help determine if you are at risk for cardiovascular complications.

6. The following risks associated with the shoulder prosthesis can occur but may be minimized if you follow the postoperative and activity instructions provided by your doctor and the physical therapy staff.
   - Loosening of the implant can occur and sometimes requires removal of the device
   - Joint dislocation/subluxation (popping out of joint)
   - Inadequate scope of movement of the implant
   - Joint stiffness
   - Joint pain (Arthraglia)
   - Joint swelling

7. Bone fracture due to weakness of bone can occur during surgery and after surgery. X-rays taken prior to surgery should help your doctor decide if you are at risk for bone fractures.

8. Temporary or permanent nerve damage as a result of pressure or bruising (hematoma) can occur during or after surgery. You must contact your doctor if you experience numbness or lack of sensation in your arm following surgery.

9. Delayed healing can occur due to infection or other medical conditions you may have. Your doctor and the research team will review your record to help determine if you are at risk for delayed healing.

Because the Eclipse is an experimental device, there may be other risks that are unknown at this time. In addition, although the Univers is FDA cleared, additional information may emerge about its safety and effectiveness and there may be additional risks with the Univers that are unknown at this time.

There are also risks related to anesthesia which will be discussed on the day of your surgery by the anesthesiologist who will be caring for you. If you have a history of medical problems, particularly problems with your heart or lungs, please notify your surgeon in advance of your planned surgery. In addition to medical clearance by an internist, you may need to have additional evaluation by the anesthesiologist or nurse anesthetist in preparation for your surgery.
III. Follow-up Visits

Postoperative Follow-up
After surgery and prior to leaving the surgery center/hospital, you will be instructed to keep records regarding your pain, medication use, postop rehabilitation and problems you may experience since surgery.

Surgical Follow-up Visits
Immediate follow-up visits will be scheduled by your doctor’s office and may be scheduled seven to 10 days and six weeks after surgery. These may include:

- Check the site of surgery
- Check range of motion
- Review ability to begin a strengthening program
- Evaluate ability to perform activities of daily living and personal care
- Discuss return-to-work responsibilities

Clinical Research Follow-up Visits
As a participant in this research trial, you must return to the clinic for follow-up visits. These visits will take place about three months, six months, one year and two years after shoulder surgery. At these visits you will have an x-ray of your postoperative shoulder and exams to measure present motion and strength of your affected shoulder.

Twelve week (three month) evaluation:
- X-rays
- Check range of motion
- Review strengthening program progress
- Evaluate activities of daily living and personal care progress
- Discuss return-to-work responsibilities
- Study follow-up activities based on informed consent

6 Month checkup:
Study follow-up based on informed consent

12 Month checkup:
Study follow-up based on informed consent

24 Month checkup:
Study follow-up based on informed consent
Surgeon’s Name ____________________________________________

Surgeon’s Telephone Number/Address __________________________

___________________________________________________________________

Hospital _______________________________________________________

Date/Time of Surgery _____________________________________________

Research Coordinator’s Name _______________________________________

Research Coordinator’s Telephone Number/Address ___________________

___________________________________________________________________

Attach Study Visit Schedule _______________________________________

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For more information on the trial please visit: www.EclipseClinicalTrial.com

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