Total Shoulder Prostheses & Hemi Shoulder Prostheses Essential Product Information

Important: This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications:
Total shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head;
3. Rotator cuff tear arthropathy. **Global C.A.P.™ is indicated for intact or repairable rotator cuff.**
4. Deformity and/or limited motion.

Global C.A.P. CTA Heads are indicated for hemi-shoulder replacement only and are to be used with Global AP Humeral Stems only.

Porocoat® Porous-Coated Components

Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue in-growth into the porous coating.

Global C.A.P. and Global C.A.P. CTA are intended for cementless use only.

Cemented Components

Humeral stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

Press-fit or Cemented Components

Humeral stem prostheses without porous coating and labeled "for press fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

Contraindications
The following conditions are contraindications for total shoulder and hemi-shoulder arthroplasty.

1. Active local or systemic infection.
2. Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components.
3. Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid.

The following condition is a contraindication for total shoulder arthroplasty.

1. Absent, irreparable or nonfunctional rotator cuff or other essential muscles.

Warnings and Precautions:
The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non anatomic loading conditions. The following conditions tend to adversely affect shoulder replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events:
The following are the most frequent adverse events after shoulder arthroplasty: change in position of the components, loosening of components, dislocation, infection, hematoma, pneumonia, and cardiovascular disorders.

Revised: 4/27/09
IFU: 0902-00-457 Rev. D