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Patient Brochure

SMR
MODULAR SHOULDER REPLACEMENT

Stemless Reverse **vs**
Reverse Shoulder System



A Randomized, Multi-Center, Prospective, Safety and Efficacy Study comparing the outcome of total reverse shoulder arthroplasty (RSA) with SMR Stemless Reverse vs SMR Reverse Shoulder System



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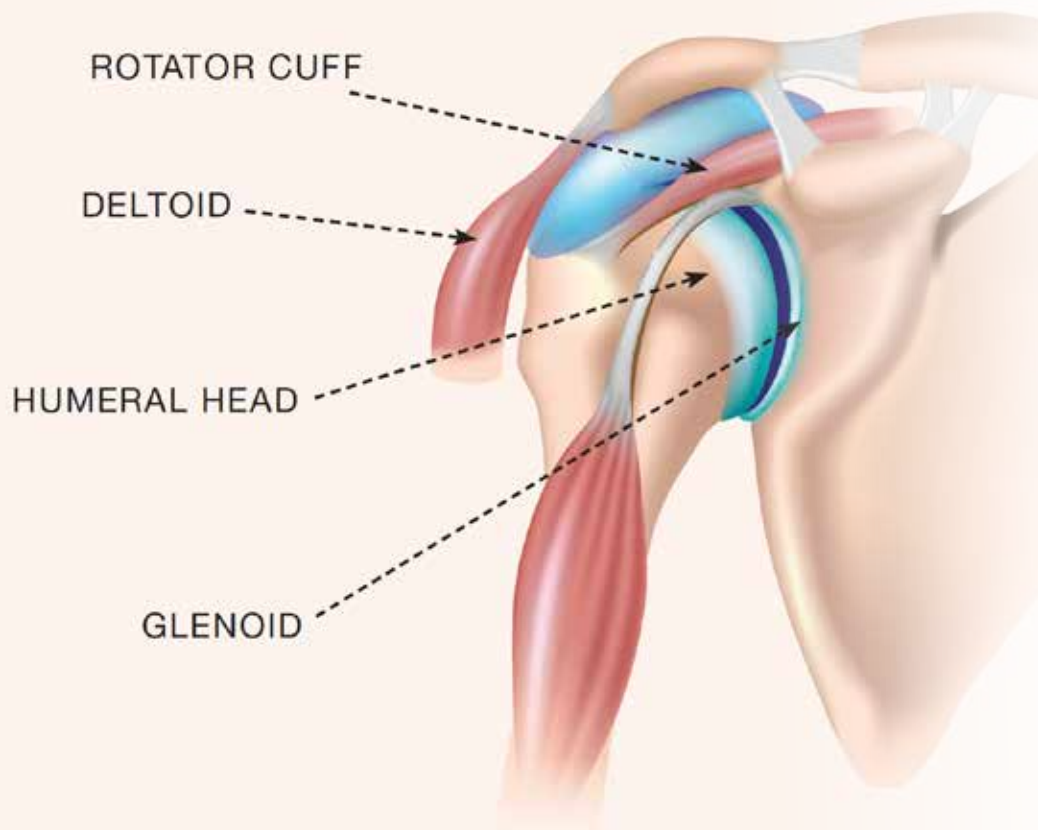


Why am I being asked to participate in this clinical study?

You are being asked to take part in a clinical study because you, with the advice and consultation of your surgeon, require a total reverse shoulder arthroplasty (RSA).

DISCLAIMER: This brochure provides a high-level explanation of the treatment and devices included in this clinical study. Fully detailed information on the clinical study can be found in the: Research Subject Consent Form provided by your surgeon's office.

The people appearing in the photographs on this publication are models and used for illustrative purposes only. This publication is not intended for distribution outside this Study.



ROTATOR CUFF

DELTOID

HUMERAL HEAD

GLENOID

Shoulder Anatomy

What are the major parts of the body that make up the shoulder?

The shoulder is a complex joint that provides the ability to perform numerous and wide-ranging tasks. The shoulder is composed of two bones and two muscle groups that help stabilize the shoulder joint and move the arm.

The **Humeral Head** is the ball shaped bone at the top of the upper arm. The **Glenoid** is the socket shaped bone where the humeral head sits and moves on. The glenoid is attached to a larger, blade shaped bone called the scapula. The glenoid and the humeral head are covered in a soft material called cartilage and this allows for smooth, pain free movement.

The humeral head is stabilized against the glenoid by a group muscles called the **rotator cuff muscles**. The rotator cuff muscles can be damaged or can wear out overtime. This is typically referred to as **Rotator Cuff tear**. The **deltoid muscle** group is responsible for the major movements of the arm.

Shoulder Pathologies

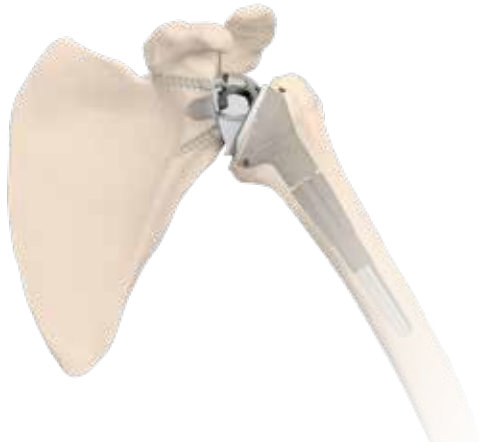
Osteoarthritis: It is a slow disease progression of bones where the cartilage breaks begin to move on each other causing pain and further breakdown of the bone.

Rotator Cuff Tear Arthropathy: It is a form of shoulder arthritis in which the shoulder has lost not only the cartilage that normally covers its joint surface but also the tendons of the rotator cuff tear which help position and power the joint.

Both osteoarthritis and rotator cuff tears may require replacement of the shoulder joint.



Anatomic Total Shoulder Replacement



Reverse Total Shoulder Replacement

What is a Reverse Total Shoulder Replacement

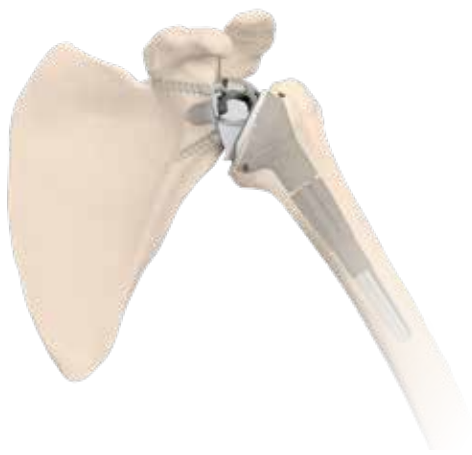
What is a total RSA?

There are several methods used to replace the shoulder.

- 1. Anatomic Total Should Replacement** An anatomic total shoulder uses a traditional replacement of the shoulder anatomy, replacing the humeral head with a metal ball and the glenoid with a thin cup of plastic.
- 2. Reverse Total Should Replacement** For a reverse total shoulder replacement, the socket and ball are switched. The ball is secured to the glenoid and the cup is fitted into the humeral head. This is to treat unreparable rotator cuff tears.

For this clinical study, a Reverse Total Shoulder Replacement will be used.

Commercially-Available Device
SMR Reverse Shoulder System



Traditional

Reverse Total Shoulder Replacement

Research Device
SMR Stemless Reverse



Stemless

Reverse Total Shoulder Replacement

Study Purpose and Device Choice

What is the clinical study looking to prove?

This clinical study is to determine the safety and effectiveness of the SMR Stemless Reverse System (investigational device). The study will compare the SMR Stemless Reverse System to the commercially available device, SMR Reverse Shoulder System.

Which device will I receive for my surgery?

The clinical study will compare the research device to a commercially-available device. This means that there is a 50/50 chance that you will randomly receive either the research device or the commercially-available device for your surgery. You cannot choose which device you receive.

Research Device: SMR Stemless Reverse has been in use outside the U.S. since 2015.

Commercially-Available Device: SMR Reverse Shoulder System has been in use in the US since 2013.

U.S. Food and Drug Administration (FDA) does not currently allow the Research Device to be used outside of this study.

Commercially-Available Device
SMR Reverse Shoulder System

Research Device
SMR Stemless Reverse



Traditional

Reverse Total Shoulder Replacement



Stemless

Reverse Total Shoulder Replacement



Lima Corporate
Orthopaedic **motion**