



Do you have a rotator cuff injury?

You may qualify to participate in a clinical research study to evaluate an investigational device for treatment of massive **rotator cuff tears in the shoulder**.

This study will evaluate performance of the MicroAire® Sub-Acromial Shoulder Implant (SASI).

SASI is a soft yet durable implant that does not dissolve. It is placed by arthroscopic surgery in the space between the top of the humerus (upper arm bone) and a bony projection of the shoulder blade directly above it (called the acromion).

Objectives of the study are to evaluate whether the device prevents undesirable bone contact, how the device is fixed in the shoulder joint, and the device's fit. Additionally, the study will determine if it improves range of motion, reduces shoulder pain, and improves quality of life.

This study is sponsored by MicroAire® Surgical Instruments.

Principal Investigator

Ronald P. Karzel, MD

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In order to participate, you must be:

- At least 55 years of age
- Have a torn rotator cuff (symptomatic torn and irreparable supraspinatus and/or infraspinatus tendons) that is non-responsive to conservative treatment
- Willing to have diagnostic imaging performed (X-ray, MRI)
- Willing to attend follow up visits at the clinic at certain points in time over the two years after receiving the device

- Participants will receive up to \$550 in compensation for attending all follow-up appointments
- Participants (or their insurance companies) will not be expected to pay for any of the procedures, for the study device, or for tests that are part of this research study
- Participants will still need to pay for their usual medical care. This would include any non-study procedures and/or non-study medication that are needed while in the study.

CAUTION: Investigational Device. Limited by Federal Law to investigational use.