

Anika's Shoulder Solutions



### Our Patients Stay Active

# The active alternative to a traditional total shoulder replacement

Have you been told you may need a total joint replacement? A total shoulder replacement can limit a person's range of motion and ability to perform physically demanding tasks. They also restrict high-level pursuits such as martial arts, weightlifting and contact sports. The Anika Shoulder HemiCAP® Implants and OVO®/OVOMotion® with Inlay Glenoid Total Shoulder Systems consist of a cap and screw that allow the surgeon to restore

only the damaged area of the joint without removing excessive bone and tissue. Your natural anatomy is preserved, allowing you to resume an active lifestyle without pain.







#### What is a joint?

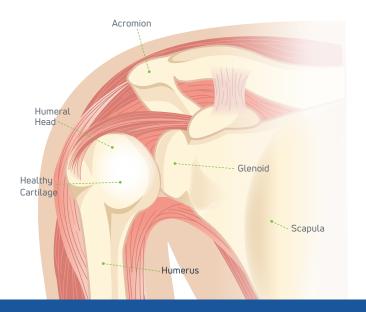
Joints are the locations in your body where two bones meet. Articulation of these bones against each other is what permits our bodies to move. Cartilage is located at the end of our bones and is a smooth, slippery tissue that allows the bones to slide against one another with minimal friction. Once cartilage is damaged, it cannot heal itself and the progressive deterioration leads to a loss of cartilage and exposed bone. Because pain sensors are located in bone and not in cartilage, it is the exposed bone that results in a painful joint.

#### How does cartilage get damaged?

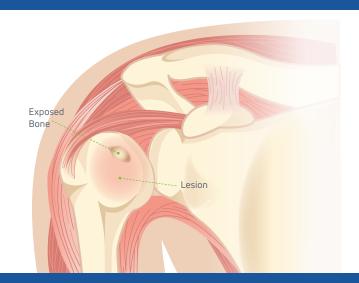
A variety of events can damage cartilage, including trauma (injury), infection, infl ammation or a joint that is not properly aligned. A traumatic injury can cause an isolated defect, while malalignment tends to cause widespread damage to both sides of the joint. This is very similar to the way a car tire loses its tread when the wheels are not properly aligned.

#### What is osteoarthritis?

Osteoarthritis is a disease process that causes the deterioration of both the articular cartilage and bone in major joints.



#### Healthy Shoulder

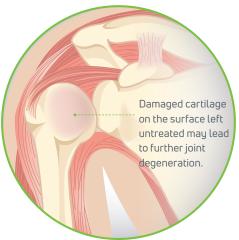


Arthritic Shoulder





10 years ago, we introduced joint preserving technologies that would allow the damaged part of the shoulder to be restored without limiting motion or removing significant amounts of bone and tissue.



Restoring the joint with an OVOMotion with Inlay Glenoid implant creates a new congruent surface. It also restores the natural anatomy of your joint.



#### Can arthritis get worse?

Any event, continued malalignment or disease process (i.e. inflammation) that injures the cartilage may cause joint damage or arthritis. A small cartilage injury may become larger and lead to widespread cartilage loss or degenerative joint disease over time. Typically, as the "wear and tear" on the shoulder joint progresses, there are bone spurs or osteophytes that form on top of the bones. These bone spurs are painful when the shoulder moves and can limit the motion of the joint. With time, the spurs become larger, the cartilage starts to wear away and the shoulder joint becomes stiff. This condition is called Degenerative Joint Disease (DJD).

#### What is osteonecrosis/AVN?

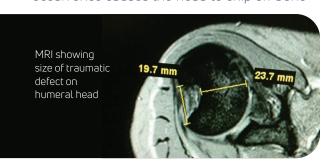
This condition is translated as "bone death" (osteo = bone, necrosis = death). Also known as avascular necrosis or AVN (avascular = loss of blood supply). Osteonecrosis is caused by the lack of blood supply to the bone, resulting in the deterioration of bone tissue and the collapse of the bone. It can be triggered by a variety of factors including trauma, alcohol abuse, genetic abnormalities, pregnancy, systemic disease or corticosteroids use from receiving medical treatment (e.g., cancer treatments and organ transplantation). However, in approximately 25% of patients the cause is still unknown.





#### What are traumatic lesions?

Damage to your shoulder can be caused by trauma, injury or previously failed surgeries. The most common type of traumatic injury is known as a "Hill-Sachs lesion." This type of lesion can occur when you have a shoulder dislocation and is a very common injury that can occur from a force pushing your arm behind you, causing the head of the humerus to dislocate from the front of the shoulder. When this happens, the humeral head turns inside its socket until the back of the head meets the front of the glenoid. This occurrence causes the head to chip off bone





and can even break a piece of bone from the front edge of the glenoid. The bone chipping can result in a lesion on the back of the head and usually causes a tear of the labrum (soft tissue bumper) on the front edge of the glenoid. The labrum is usually repaired arthroscopically. The surgeon reattaches the torn soft tissue (labrum) using suture and anchors.

When 30% or more of the head is chipped off, the Hill-Sachs lesion is sufficiently large enough to engage or catch on the front of the glenoid. While not all Hill-Sachs lesions are painful, this catching can result in a sore shoulder and severely limit your motion. Over time, the repetitive catching can re-tear the previously fixed labrum. To stop this from happening again, the surgeon may fill the defect on the back of the humeral head so it stops catching. This can be accomplished by placing a HemiCAP° implant into the defect, restoring the shape of the humeral head and allowing it to articulate smoothly again without catching.

Another type of traumatic lesion can occur when the anchors used to fix soft tissue damage in your shoulder (i.e. rotator cuff repair) loosen and rub against the humeral head. This tears the surface cartilage, resulting in exposed bone and a painful lesion. A shoulder HemiCAP implant can restore the joint by being placed into the damaged area, covering the defect. This seals off the exposed bone to create a new smooth surface.





### What are treatment options for damaged cartilage?

Depending on the degree of cartilage injury, the age of the patient and the level of activity desired, patients may be candidates for: microfracture (marrow stimulation), grafting, injections, an Anika HemiCAP® or a traditional total joint replacement.

#### What is microfracture?

In a microfracture procedure,

a surgeon uses a pick or an awl to create holes in the exposed defect that will cause bleeding. This will initiate a fibro-cartilage healing response. The fibro-cartilage then grows and fills the lesion creating a new surface. This response is similar to a "scar" or the way a scab grows over a cut. This technique may provide short-term pain relief and is generally indicated for patients under 35 years old. The rehab for microfracture can be lengthy and involve minimal weight bearing for weeks. Do not expect a full return to activity until at least one year post surgery.

#### What about grafting?

Allografts are human donor tissues. Unless the allograft is "fresh," meaning that it has not been frozen or treated with a variety of preservation and other processes, the cartilage surface on the donor tissue is inactive. In essence, it is a bone graft and not a cartilage graft. Fresh allografts are available but they are difficult to find and are limited to key sites in the United States.

The surgeon uses shoulder bone that is roughly the same size and shape as your humeral head and then creates a graft that will fit into the damaged area to be replaced. This is a diffiult surgery because it is very hard to match each patient's individual surface curvatures. There is also a small risk of disease transmission and there are lengthy wait lists for grafts. Outside of the United States, grafting is limited or non-existent.





# I've heard of injecting cartilage cells to regrow normal cartilage. Does that process work?



This is an option where a cartilage biopsy is taken from the patient and sent to a lab where new cartilage cells are grown. The patient returns for a second surgery and the cells are placed in the damaged area and covered with a tissue patch so the cells stay in place



Traditional total shoulder stemmed joint replacement



Anika HemiCAP Implant

until healed. This procedure is rarely used in the shoulder, due to very thin cartilage. There is not enough depth to inject cells without making the surface uneven. Some downsides of this procedure include: varying results, multiple surgeries and expensive costs because it is not always covered by insurance. Also, the rehabilitation can be long and difficult. Almost half the patients require a third surgery to address further issues.

### What about a traditional total shoulder replacement?

This is a major surgery designed to relieve the pain of widespread arthritis. It removes the head of the humerus, the rotator cuff and significant amounts of bone from the glenoid. Also, other supporting tissues are compromised. Total joint replacements were originally indicated for patients over 65 years old who had a sedentary lifestyle. Because this is an artificial joint, your motion will no longer feel normal and activities will be severely limited (i.e. lifting, throwing, contact sports). In younger patients, tradditional total shoulder replacements have a lifespan of approximately 10-12 years, possibly leading to a future revision.





### What about restoring my joint with Anika?

Restoring a joint with an Anika shoulder implant is considered the active alternative to a traditional total shoulder replacement. The idea behind the HemiCAP® & OVO® systems is to relieve the patient's pain while preventing further damage to the joint and maintaining the patient's natural anatomy and motion.

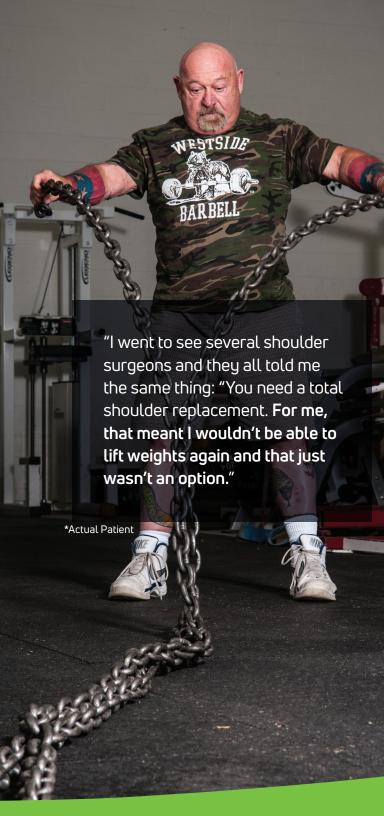
The implants consist of a cap and screw that lock together via morse taper. The cap is a contoured surface that goes over the area of damaged cartilage and is designed to protect the remaining, healthy cartilage in the joint with minimal bone removal. The Anika screw system has been a stable construct with no reported loosening over the last 14 years. The HemiCAP is indicated for the treatment of patients with the following clinical conditions: avascular necrosis and post-traumatic degenerative disease.

The HemiCAP procedure is a technologically advanced system designed to match the shape and contour of the individual patient's

cartilage surface. The HemiCAP matches not only the diameter of the damaged area but also the precise radius of both curvatures on the patient's joint surface, superior to inferior (top to bottom) and medial to lateral (side to side). Once the mapping points are defined, the appropriate implant is chosen and is then placed into the patient's joint.

For patients with widespread arthritis in their shoulder, Anika offers the OVO and OVOMotion® with Inlay Glenoid Total Shoulder System. These systems help preserve most of the bone in your shoulder while also fixing any damage to your glenoid. Unlike traditional total shoulder replacements, the Anika stemless total shoulder systems are anatomically correct, improve range of motion, reduce pain and do not limit any future activities such as weight-lifting. The Anika solutions restore the joint with the largest diameter humeral implant and an inlay glenoid implant. Inlay means that it is implanted into the bone rather than on top, leaving natural bone to support the implant around its edges while leaving the natural shape of the joint intact. The OVO & OVOMotion, simply places a smooth metal surface on the humeral head where the cartilage has worn away as well as a plastic glenoid implant placed with bone cement on the opposing side.







#### A patient's story

"Being a former Senior Power Lifting Champion and owner of a prestigious power lifting gym, it is crucial to my work and life to be able to use my shoulder. For the last 11 years, I have had to live everyday with pain in my shoulder. In the last few years, it got so bad that I couldn't sleep more than a few hours at a time without being awakened by the pain. In fact, when I would drive my truck, I would have to use my left arm to change gears and even the radio station because it hurt so much to use my shoulder.

Finally, someone referred me to a doctor who might be able to help. He was trained using a device called a HemiCAP implant that would restore my joint rather than replacing it."

"Using the HemiCAP implant, the doctor was able to reconstruct my shoulder without compromising any of the muscles and tendons."

"Not only did the pain go away in a matter of weeks but also for the first time in over 10 years, my shoulder works and feels like normal.

Given my history, that is nothing short of fantastic! My pain is gone, I sleep through the night and I am back to full time lifting and working out. Without my surgeon and this technology from Anika, I would have had to stop doing what I love the most — lifting and training athletes to get powerful and strong."

- Louie





# How are the HemiCAP & OVO implants different from traditional total shoulder systems?

- They are custom matched and fit to the patient's joint size and shape
- · Screw fixation provides a stable implant
- Significantly less cartilage and bone is removed than traditional joint replacements
- It is placed into the surface rather than on top, leaving the joint less surgically altered
- Joint motion and natural anatomy of the shoulder is preserved resulting in No Activity Restrictions
- May be performed on an outpatient basis.
  Less time in the hospital.

### How long will the HemiCAP & OVO implants last?

Your surgeon expects the device to last as long as similar metallic devices. However, it will depend on your general health, activity level, and adherence to your doctor's orders following surgery. Currently over 100,000 patients have been treated with Anika implants and many have hit the 10 year mark!

#### What happens if it fails?

If it ever fails, it may be replaced with a total joint replacement.

#### Does it "burn any bridges"?

There is minimal bone removed with the HemiCAP® & OVO® implants, while existing joint replacements surgically remove the entire bone surface (on both sides of the joint). This means there is far less of the natural bone to work with if future surgery is required. The HemiCAP & OVO systems leave more bone intact, therefore providing more options should future surgery be required.

#### Will I feel it?

No. The implant is surgically placed so there are no protruding edges. The bone and the implant become a smooth surface you will not feel.

#### How long will I be out of work?

This will depend on your overall health, range of motion and the type of work you do. Many patients have experienced a rapid return to daily activities. However, as with all medical treatments, individual results may vary.

#### Will I need physical therapy?

Your doctor and therapist will design a rehabilitation protocol to return strength to your muscles so you can resume your original lifestyle as quickly as possible.



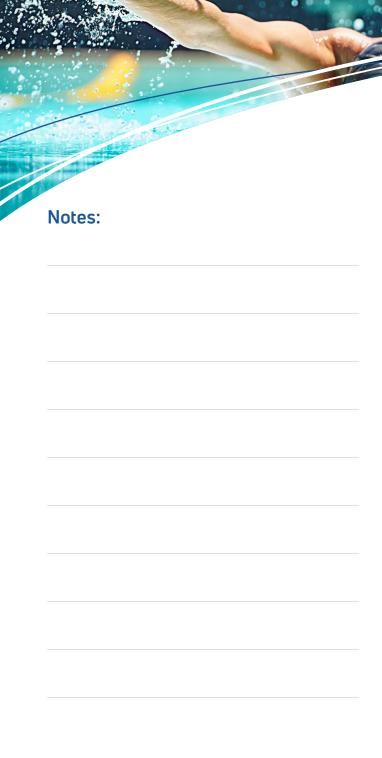
### Questions to ask your doctor during your visit

- Will my joint feel normal and move naturally after I have the surgery?
- Will you remove the head of my shoulder bone or my labrum to put in the implant?
- Is my cartilage damage localized?
- · Is the alignment of my joint close to normal?
- · Is my joint unstable?
- · Do I have any joint space remaining?
- · How long will I be hospitalized?
- Can the procedure be performed on an outpatient basis?
- · Will the recovery take weeks or months?
- Will I be able to lift weights and if so, how much?
- Can I go back to all my previous sports and activities?

#### Are you a candidate?

- You want to regain your active lifestyle
- You have had a microfracture treatment or injections, but the pain has returned
- You cannot afford lengthy rehabilitation time or excessive time off work
- You want to fix your shoulder problem now versus waiting for your shoulder to undergo further damage
- Your surgeon has told you that you will need a shoulder replacement in the future





Notes:	



#### To find a doctor near you, call 1-508-520-3003 or visit www.anika.com/find-a-doctor

Due to its general applicability, do not rely on information in this brochure to assess any particular patient condition. Individual results may vary. Seek professional medical advice for specific personal care. Do not delay seeking professional medical advice or disregard professional medical advice because of something you have read in this brochure.

#### arthrosurface

Arthrosurface has joined Anika

#### Anika Therapeutics, Inc.

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