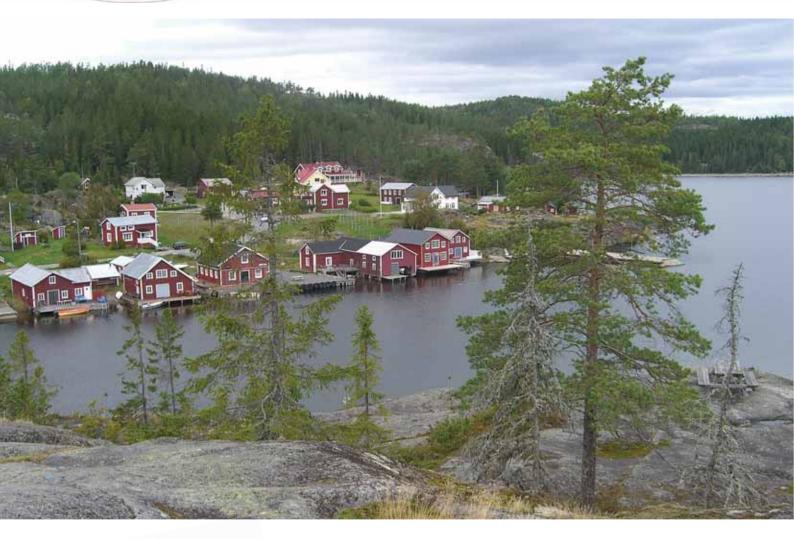


Patient information





Your new shoulder joint

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Introduction

Maybe you have been diagnosed with a degenerative joint disease or a fractured proximal shoulder. Especially when conservative treatments have failed or have not led to any permanent improvements joint replacements are often the best option. Shoulder disorders are very painful and in many cases effect the patients entire daily life, which makes surgery with an artificial new joint inevitable.

Even though joint replacements are common most people do not occupy themselves with it till they are effected themselves or the people they hold dear. This brochure is intended for patients that need an artificial shoulder joint. It is intended to explain the principles of both the shoulder anatomy and shoulder endoprosthesis. Your new implant is explained and you will get some information concerning the procedure before, during and after surgery. Tips and exercises for the time of recovery can be found at the very end of this booklet.

This pamphlet is intended as an addition to your consultation with your physician. It is supposed to educate you about the surgery and help resolve your worries and concerns.



The shoulder joint

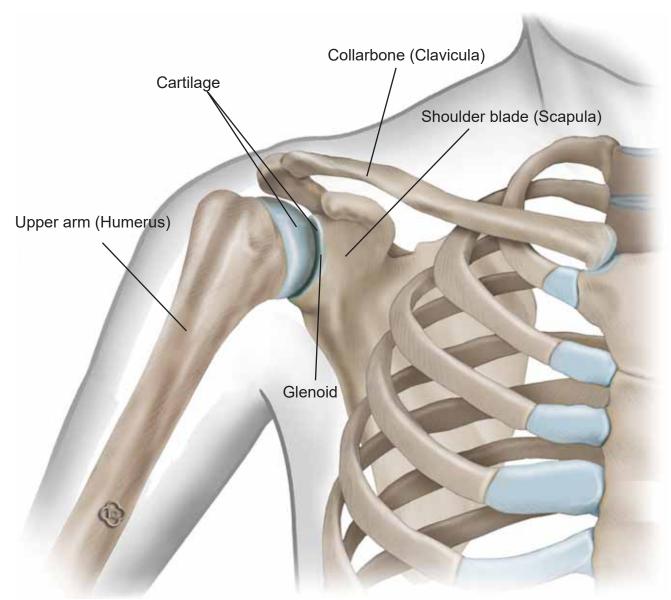
The healthy shoulder joint has the greatest range of motion among all joints in the human body. It enables movements and rotations in various directions. Without it we couldn't use our arms and hands as effectively as we do.

In order to allow this wide agility the shoulder is less constrained by surrounding bones in comparison to other joints. Instead muscles and tendons play an outstanding role.

The shoulder is comprised of three slim bones: The upper arm (Humerus), the shoulder blade (Scapula) and the collarbone (Clavicle). The shoulder blade forms an oval articular cavity (Glenoid), which forms the articulating surface for the head of the upper arm. The humeral head has approximately the triple size of the glenoid to allow wider range of motion. On both sides the articulating surface is covered with a cartilage layer.

Like all joints the shoulder is surrounded with a capsule, which produces joint fluid to lower friction. It also serves as nutrient fluid for the cartilage.

Muscles, tendons and ligaments hold the bones in place and form a so called "rotator cuff" around the joint capsule.



Wear of the shoulder blade - osteoarthritis

Wear of the joint (osteoarthritis) means, that the cartilage is damaged and worn down. A smooth movement is not possible anymore and the patient is suffering from severe pain. Osteoarthritis in the shoulder is called omarthrosis.

The ever increasing age alone is leading to wear - so called idiopathic arthrosis. Thus, to some extend degenerative cartilage is normal at a certain age. However, not everyone needs a joint replacement in life. Often omarthrosis occurs due to overstress or in combination with metabolic diseases, rheumatic diseases or infections that damage the cartilage.

Usually the damage on the cartilage progresses slowly over many years. The cartilage is getting thinner and thinner, cracks occur and the formerly smooth surface frays and becomes rough. Painful inflammations and effusions are often the implications. Once the bone surface is not covered anymore and

seamless motion is impossible patients start to suffer even without movement. Sometimes the body tries to compensate the damage by bone proliferation. This increases the contact surface, but does not solve the problem. Instead most of the times it increases the progression of the disease.

Because usually only late stages cause severe pain conservative treatment options are often not effective anymore.

In almost all cases the main symptom for osteoarthritis is severe pain. In early stages start-up pain after not moving the arm for a longer period are usual. The pain increases in the progress till it occurs at rest.

Since cartilage, unlike most other tissue, does not regenerate on its own, in many cases with advanced osteoarthritis artificial joint replacement is the most successful to regain motion and gain freedom of pain.



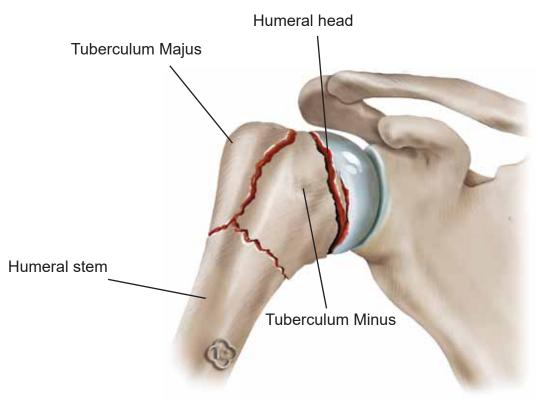


Arthrotic shoulder joint

Humeral head fracture

Accidents and unfortunate stumbles that lead to a fall that impacts the shoulder joint can cause fractures of the upper arm (humerus). Some sports like horseback riding, skiing or cycling are more prone for humeral head fractures. Strong impacts are especially dangerous for the humeral head, because they often lead to complicated multi fragmental fractures. Patients that suffer from osteoporosis are under a higher risk to suffer this injury. Between two and four part fractures are usual. Often each fragment is attached to a different tendon and pulled in another direction.

After conservative treatments or plate and screw solutions have failed or if they are unlikely to be successful, surgery and a new artificial shoulder joint is the best and often only option. A specific trauma prosthesis is used which allows the surgeon to fixate the fractures around the implant. The damaged articulating surface is replaced as well. Because the shoulder blade is often not harmed by the accident a one-sided endoprosthesis (hemi-prosthesis) is often enough. And the artificial humeral head can articulate against the natural glenoid.



Shoulder joint with 4-part fracture

Rotator cuff deficit

As previously discussed, the shoulder is soft tissue guided. Tendon of four different muscles surround the joint. This so called rotator cuff applies permanent tension and stabilizes the joint. They also enable a rotatory motion within the articular cavity. In case of wear or even a major tear, that can't be sewed together, the shoulder can't be moved as intended anymore. The necessary guidance is missing. It is also possible, that the humeral head is misplaced and moves out of the cavity. Patients who are

exposed to high physical burdens such as construction workers or professional athletes are more likely to suffer from these damages in the rotator cuff.

Constraints in range of motion and severe pain are inevitable. The defective guidance can be substituted with an inverse prosthesis. The special geometry and features of this implant are described on page 9.



Treatment with an artificial joint replacement

If conservative treatment options such as physiotherapy have failed and severe pain is influencing the daily life surgery and a replacement of the joint with artificial components is the only valid option. Joint pain often effects the entire life.

The main goal of the surgery is to gain freedom of pain. Additional an increased range of motion is achieved in most cases.

A Shoulder joint replacement will never be able to reach the perfection of a healthy natural shoulder. But modern endoprosthesis are often able to reach results, with very little constraints for the patients daily life. Without permanent pain, life quality is back on an entirely different level.

Anatomic endoprosthesis

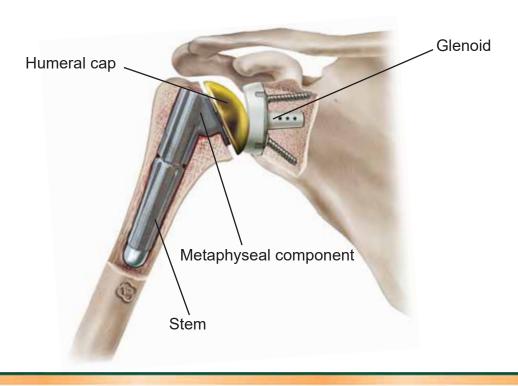
In most cases shoulder osteoarthritis is treated with an implant that rebuilds the natural anatomy as exact as possible. If the cartilage is damaged on the humeral side only a hemi-prosthesis might be sufficient. If the glenoid is also affected a total endoprosthesis is the best option.

The AGILON® shoulder system by implantcast stands out by its total modularity. The modularity gives the surgeon the ability to customize your implant specifically matching your anatomy. In most cases the implant consists of a stem, a metaphyseal component (a middlepiece that recreates the anatomy of the upper arm), a screw to connect the pieces and a cap that replaces the damaged cartilage and creates a new articulating surface. Different sizes of all components combined with different neck angles and various rotational offset options allow an outstanding individual adjustment. There are two ways to fixate the stem in the bone: Either bone cement (PMMA - a biocompatible polymer) is used to glue the implant and the bone together or a pressfit holds the stem in place. Both techniques require specific implants that were developed for that use only. Your doctor is going to discuss what is best for you.

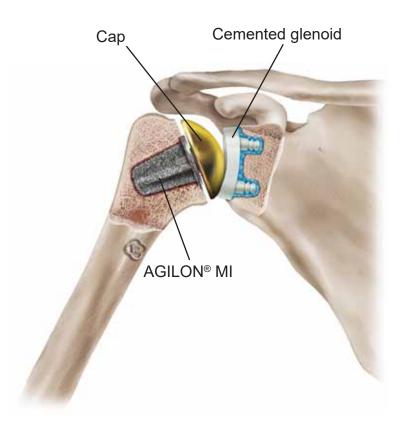
If a total joint replacement is planned a glenoid

component is used to replace the articulating cavity on the shoulder blade. Your doctor is going to plan the surgery ahead using x-ray images. The size of your bones will predetermine the sizing of the implant. During surgery the trial components are used to figure out if the planning was correct and to achieve the best adjustments possible. Adjustments are both wanted and needed in order to get the best results possible.

The golden caps made out of a ceramic coated titanium alloy are available with different diameter and heights and have an offset that can be adjusted in different positions. Most humeral heads have a unique shape, which is similar but not identical to others. Therefore adjustment options to each individual anatomy are important. The glenoid on the shoulder blade can either be made entirely out of Polyethylene and fixed to the bone with bone cement, or a modular variant that consists of a titanium base with a polyethylene insert. The modular version has an advantage because in case a revision of the implant becomes necessary, replacing single components is possible and the stem can be left in place. No further damage to the bone is necessary.



Stemless Implants



If your bone structure is in a good condition your surgeon might opt for a stemless implant. The AGILON® MI is a modern 3-D printed titanium alloy implant. The porous EPORE® structure was developed in an attempt to mimic the structure of cancellous bone. The unique structure allows bone to grow into the implant and increase the long term fixation. MI stands for metaphyseal implant, which refers to the bone area, in which the implant is anchored.

This implant is especially suitable for young patients.

Your physician is going to choose the best matching implant from a variety of sizes.

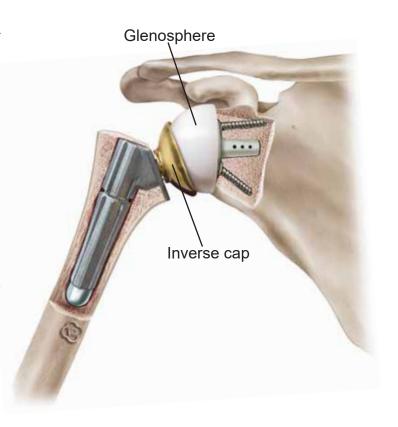
On top of the implant a ceramic (titanium nitride) coated metal cap replaces the articulating surface. The head can be precisely adjusted with different heights, diameters and rotational offsets. It can be used in combination with the above mentioned glenoids or on its own as a hemi-prosthesis.



Inverse endoprosthesis

In case of an instable shoulder joint, which is often caused by a major rotator cuff tear. It is possible to reverse the natural anatomy of the shoulder. Usually a ball shaped component is on the upper arm side and a socket on the shoulder blade. Inverting this geometry increases the support offered by the implant. "Dislocation"- the ball jumping out of the socket is less likely and the implant is less reliant on a working rotator cuff. Instead more guidance is provided by the implant and the shoulder muscle (deltoid) that has a different angle of attack than before. The inverse caps are designed in a slim manner to prevent bumping against the shoulder blade. This so called "scapula notching" is one of the major reasons for inverse prosthesis to fail. The unique AGILON® design minimizes this risk. It allows an increased range of motion as well.

A reversed endoprosthesis design can also be the best option for patients with complicated humeral head fractures.





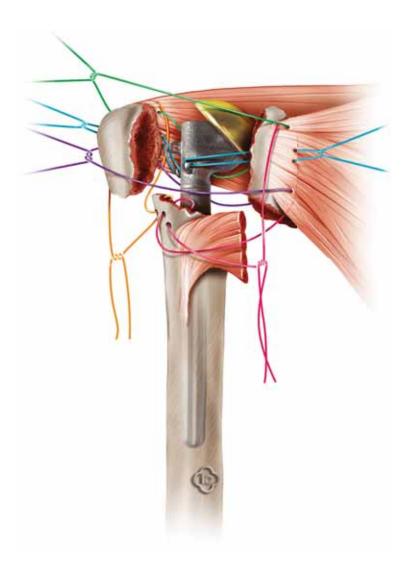
Trauma prosthesis

The fracture implant was specifically developed to rebuild the damaged humeral head. Humeral head fractures are complicated because the attached muscles pull each tubercle in a different direction. In order to restore the function of the shoulder joint, the fragments need to be connected to the endoprosthesis.

The implant is designed in a very slim manner, which allows your doctor to attach the bone tubercle to the side of the implant. High strength suture material is used to fix the parts in the right positions. Eyelets on the implant allow an easy and permanent connection between the

bone and the implant.

In some cases the accident that led to the fracture of the humeral head also damaged the shoulder blade. In those cases the fracture prosthesis can not be used as a one-sided hemi-prosthesis. Instead the shoulder blade needs treatment as well. Two options exist to replace the damaged cartilage. Either a polyethylene glenoid component can be fixed with bone cement, or a titanium base can be used. Both options have proven to be good and valuable. Your physician will decide what is best for you specifically.





Things to know around the AGILON® shoulder system

implantcast GmbH, the company formed in 1988, is one of the specialists in its sector with regard to development, construction and production of joint replacements. Its core competence lies in the manufacturing of endoprosthesis as functional joint replacements, specialist implants and customized products.

Constant investments in the location, highest quality "made in Germany", qualified employees and its specialized services are the fundamental pillars of our company success. First class quality, innovative spirit and willingness for permanent improvements lead to our modern, well tested and proven implants.

Your doctor will decide based on the damage of your shoulder joint whether a total shoulder replacement (surrogate of both sides of the joint) or a partial shoulder replacement (hemi-prosthesis, replacement of one side of the shoulder joint) is required. In some cases the surgeon may need to surgically assess the damage prior to selecting the appropriate implant type.

Depending on the size of your shoulder joint there are matching sizes of the prosthesis available. The AGILON® shoulder system provides multiple adjustment options and additional extension possibilities, which allow the AGILON® to be adapted to suit your specific requirements. The system offers a comprehensive range of treatment options in one carefully proven design.

Revisions are not uncommon with artificial shoulder joint replacements. The total modularity of the AGILON® shoulder system allows a very easy conversion without the need of changing the stem or glenoid component. This can be beneficial because the shoulder blade is a thin bone and each further infringement risks the stability of the artificial joint. Your surgeon does not need to sacrifice an unreasonable amount of healthy bone and is able to rebuild the same implant length as before - "conversion in a blink".



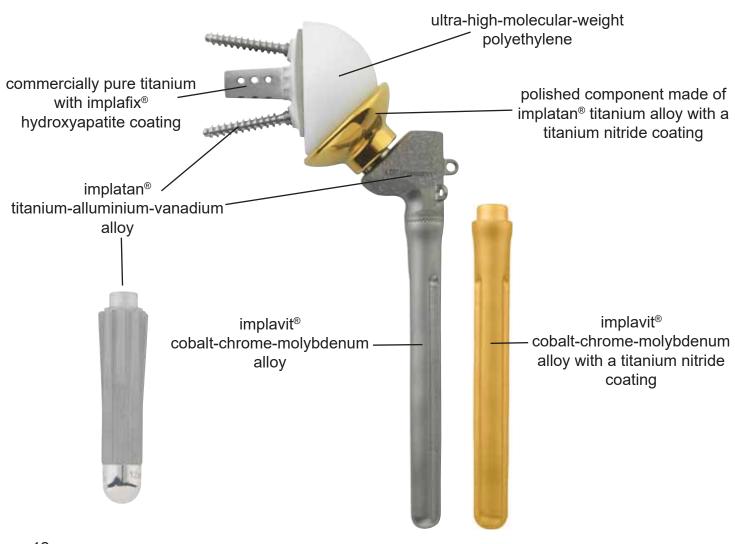
Materials and metal allergies

Most metallic components of the AGILON® shoulder manufactured are from biocompatible titanium alloy. The articulating parts are covered with an app. 5.5µm thin golden ceramic coating (titanium nitride - TiN). The coating has the advantage that the friction and thus the potential wear between the components is minimized. The reduction of friction improves the wear-properties of the pairing, and this in turn, can improve the longevity of the AGILON® shoulder replacement in your body. The cemented stems are made of a cobalt chromium casting alloy. They are also available in a TiN coated variant. The coating also forms a protective barrier against the release of metal ions, which can cause allergic reactions in some people.

The implants below the coating meet all requirements a shoulder implant has to fulfill, but we at implantcast believe that the benefit the coating brings should be standard on all our implants rather than a bonus for few.

The plastic components (PE-glenoids, PE-Inlays and glenospheres are manufactured from an ultra high molecular weight polyethylene (UHMWPE), which is a plastic specifically developed for use in joint replacements.

Prior to surgery your physician is going to talk to you about known allergies, to avoid potential complications. If need be he is going to react with the appropriate implant choices.



Potential risks and complications

Implantation of a shoulder endoprosthesis is a routine surgery and has proven to be successful. However every surgery, even the smallest, carries a not negligible risk. Thus, prior to every operation all benefits and risks must be considered. In most cases the outstanding benefit is a freedom of pain that elevates life quality to a higher level. Additionally most patients recognize an increase in range of motion and sometimes power.

A distinction is made between a specific and a general risk. The general risks apply to the surgery while specific risks are caused by the implant. Thrombosis or embolisms are examples for general risks that the physicians try to limit with blood thinning pharmaceuticals. Infections as well as damages to the vessels or nerves also belong to this category. Due to modern techniques and the vast experience those risk have become unlikely.

Agglutination and adhesions in the shoulder joint belong to the specific risks that can occur if the shoulder is not moved sufficiently in the first days after surgery. In very few cases calcifications in the muscles, that result in pain, limited movement or both have been observed. If the new artificial shoulder joint is used

appropriately, high loads are avoided and the surrounding soft tissue is in a good condition, chances for a long lasting implant are very bright.

However an artificial joint will never be able to reach the perfection a healthy joint has. Overloading should be avoided. Sport disciplines that are challenging for the shoulder are not appropriate.

If loosening or wear of the prosthesis parts occur for any reason, a revision with an implant swap is necessary. Revisions like that are easier if the system is modular because it allows the surgeon to react to the damage by more constrained variants, or inverting the geometry as mentioned before without having to remove the stems.

Revision surgeries are common and can be complicated. The modularity simplifies and shortens surgeries significantly.

Your physician is going to talk to you in dept about risks and benefits related to your surgery. He will be pleased to answer all questions you certainly have. Surgery is your final decision and should be taken after careful consideration of all factors involved.



Before and during surgery

It is important to be in a good general health condition before your surgery. If you are under permanent medication for diabetes, cardiovascular diseases or others, your doses should be well adjusted. All infections need to be examined and treated before the operation because they may carry an increased risk. In most cases the implantation of an artificial shoulder joint is a planned intervention and you are able to prepare yourself in an holistic approach. We highly recommend taking a few arrangements - reading this brochure is a good first step in the right direction. Taking care of a healthy lifestyle and getting in shape if you are overweight is helpful for better chances of success. Pack a bag with your personal items, toiletries and clothing to wear for the time you are going to be in the hospital.

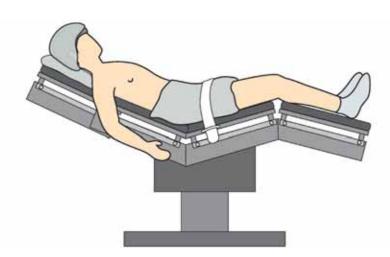
You will benefit greatly, if you have some assistance with cooking, bathing, housekeeping, shopping, etc. during the first several weeks

after surgery. Do you have a family member, friend or professional care giver who will be able to help?

It is also helpful to take a few preparations at home. You physician or physiotherapist is going to advice you on helpful gadgets such as shopping cards or trolleys.

Place items and goods that you need on a daily basis on places that are easy to reach. Waist height is ideal. Prepare as much as possible so you are able to go easy afterwards. You might want to consider preparing some meals prior and store them in the freezer to have them ready after surgery.

The operation will usually take place under general anesthesia. Your anesthetist will explain your options and consequences prior to surgery. In most cases it is important to have an empty stomach, so that the narcotics have an ideal effect.



During surgery you are positioned on your back in the so called "beachchair position". Your surgeon approaches the shoulder joint from the site. After exposing the joint damaged cartilage as well as a part of the humeral head are removed. The remaining bone is shaped with special templates and instruments in a manner that matches the components best suited for your anatomy.

Ligaments are left unharmed to allow close to natural motions after surgery. After using trial components to find the best fitting components, the final implant is inserted.

Nowadays surgery for shoulder joint replacement is a routine procedure. After approximately two hours surgery is complete and the wound sewed back together.

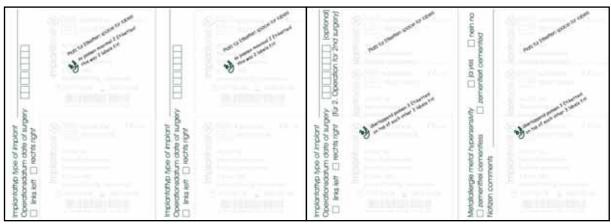
Your patient / endoprosthesis pass

When discharged from the clinic you will receive your patient / endoprosthesis pass. The pass contains important details of your new shoulder joint replacement, e.g. the used implant components and the date of surgery. Always carry this pass with you.

In case of potential joint injuries or complications it could be very helpful for your doctor to have information available. It might also be required for security checks for example at the airport.







After surgery

Post surgery the arm is supported by a sling that prevents harmful motions. Cooling pads can be used to reduce swellings. As soon as possible lymph drainage and mobilization are performed to prevent further swelling of the wound and irritated tissue. One day after the operation you will be able to walk around your room on your own. However for the first days it is recommended to spend as much time in bed with an elevated upper body, as possible in order to reduce pain. It is important to follow your surgeons instructions. If you have questions feel free to discuss them with your doctor prior to hospital discharge.

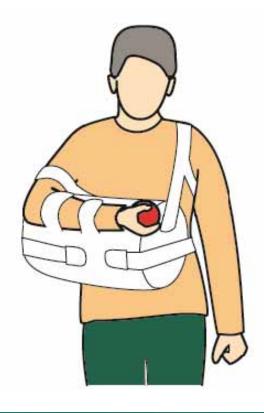
Tubes that are put into the wound to allow fluids to drain are removed at day two or three. Often a second x-ray based control and blood test is carried out. Pain medications as well as blood thinning medications are going to be prescribed to you for a few days.

Physiotherapists are going to help you to gain a good range of motion and rebuild your arm

strength. Your physician decides about the ideal timetable for physiotherapy depending on the surgery and your condition.

Starting on day two or three a therapist is going to exercise with you on a regular basis. During the first two weeks most exercises are passive, which means your therapist moves your arm in a controlled manner. The range of motion can be increased continuously.

Your physiotherapist is going to perform exercises that aim to build up your muscles and stabilize your shoulder. Gaining a good range of motion is also a major target. Most of the time this treatment is carried out ambulatory. Between week three and six exercises become more and more active. As early as week seven you won't need a bandage anymore. In week eight the exercises are increased one last time. Your therapist might use tools to increase loads in later stages.



Back to your daily life

After surgery moving is going to be easier day by day. Nevertheless the first period is challenging. Once you are home there are going to be some tasks that require help. It is important to prevent overloading your new endoprosthesis shortly after surgery. The following movements should be avoided:

- · Sudden movements
- High weight loads
- Carrying load especially with the arm straight ahead.
- · Working overhead

 Minimize the risk to fall (if an accident occurs) contact your physician immediately.

The following illustrations are meant to help you in everyday situations. They show common movements you should be aware of and how to move in a non harming manner.



Sleeping

In the first approximately six weeks you should wear a sling to prevent uncontrolled motions during sleep. Sudden movements could endanger the fresh sutures of the muscles and tendon. In most cases patients prevent those

movements on their own because they tend to be painful. Sleeping on the side should generally be prevented as well because it is painful. However it isn't harmful and thus not forbidden.



For ten to fourteen days the wound has to stay dry. You should use special bandages when showering to protect your wound from infections. After the sutures are removed you

are allowed to shower without bandages. Try not to lift your arm further than you are able to without pain.



Washing your hair

In the time directly after surgery your range of motion is going to be limited severely. You will need help washing you hair and drying it. Be patient it will take two to three

month and a lot of exercises till you reach your entire range of motion. Once you are there you will be able to handle these difficulties on your own.



Brushing ones teeth

For a few weeks you will be unable to brush your teeth with the arm that has the new artificial joint. Your range of motion is going to be insufficient and the sudden movements

are too painful. Use your healthy arm. An electric toothbrush is useful if your strong hand is challenged and you are too clumsy with the other.





Shopping

Your new joint should not be burdened with additional load for eight weeks. Shopping bags can be heavy and you should consider using a backpack or trolley. Later it is best to keep

the new habit with backpacks or trolleys. If you prefer shopping bags. Use smaller ones and carry them separately to keep the stress on your shoulder low.

Toilet

In the first weeks it is not possible to rotate the arm inwards. Wiping with the treated arm is not possible. Instead you will have

to use the healthy side. Even though this can be challenging at the start you shouldn't be reliant on other people's help.



Dressing and undressing

If possible use your treated arm as little as possible and rather use your healthy arm. It can be helpful to use shoes that do not need to be tied and where you can slip in without problems.

When you are dressing with a shirt or jacked pull the garment over your treated

arm first and continue with the other side. For undressing first take out your healthy arm first to create room for motion and afterwards stripe the jacket of the treated arm. Avoid clothes that need to be pulled over the head. Loose fitting clothes, that open in the front are best suitable.

Driving

As long as your arm is in a sling and does not have its full strength, you shouldn't be driving a car. It is dangerous for you and others and in case of an accident the insurance might not cover the damage even if it wasn't your fault. Usually you can start driving from week seven

onwards. However it is recommended to discuss this issue with your physician previously and test the motions necessary for steering and shifting before entering into traffic.



Sexuality

You should be careful in the first weeks after surgery. Heavy loads and strong

flections should be avoided.

Exercises for at home

With artificial joints it is best to stay active. Sports that are gentle for the shoulder are best. Generally sport with little strain and a continuous movement like walking or cycling are recommended options. Six to eight weeks after surgery your recovery should have advanced far enough that your joint is stable again. Step by step you will be able to use your arm for all daily activities.

The following exercises are ment to help you regain range of motion and strength. They aim at strengthening certain muscles and move the joint in all directions. Both your physician and your physiotherapist are going to talk to you which exercises are best for you. Carry out the exercises as described and stop as soon as you feel any pain or restrictions.

19

| 1. Lower and posterior joint capsule. Use your healthy arm to guide your tree. The exercise is meant to stretch the lollimit, but not any further. | eated arm forward and upv | | |
|---|--|--|--|
| 2. Front and rear joint capsule Put your flat hand on your tummy your stretched hand forwards until the stay in contact with the torso at all tim helpful to place a sheet of paper between to stretch the front and rear part of the daily. | finger tips point forwards. es. For a correct performa en the body and upper arm | Your upper arm should nce of the exercise it is . This exercise is meant | |
| 3. Lower arm muscles As soon as your doctor agrees you should rubber ball or sponge multiple times a dispersion of the sponge muscles this exercises swelling and helps recovery. | lay. Press-together and rele | ease the ball repeatedly. | |
| 4. Upper arm muscles The upper arm muscles should be tracelbow and pull your forearm towards your body. Weights are not needed to | our chest, while your upper | | |



5. Internal and external turning muscles

times daily

repetitions

This exercise is meant to strengthen the muscles for internal rotation. Position yourself next to a door or wall. Your elbow should be in a 90° angle, your upper arm in contact with your body and the fingertips pointing forward. Press your arm carefully against the wall. There should be as little motion in the joints as possible. Pay attention to keeping the contact between upper arm and body without building pressure. Hold the tension for six seconds. To strengthen external rotation repeat the exercise from the other side.



6. Lifting the arm with bend elbow

times daily

repetitions

When the shoulder muscles are strong enough to stabilize the joint dynamic motions can be performed after consulting your doctor. Bend your elbow 90° and lift your bend arm forwards. Perform the motion as far as you are able to without pain. Spreading the arm sideways is the most challenging movement for the joint and creates the highest tensions. Consequently sideways motion should be kept to a minimum in the first time after the surgery. Once your physician agrees you can start doing this exercise sideways as well. The weight of the arm alone is sufficient.



7. Internal and external turning muscles

times daily

repetitions

Once sufficient stability is achieved you can use an elastic theraband in order to increase load for some exercises. Lay the theraband around a door knob and carry out a slow 90° motion of the arm. Stick a paper between your body and your arm for improved posture.



8. Internal and external turning muscles

times daily

repetitions

Pull the band around a door knob once again. Position yourself frontal to the door. Position yourself similar to exercise 7. Start in the middle and move the arm towards your stomach. The highest tension should occur when the arm is in front of the tummy.



| Notes: | | | |
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