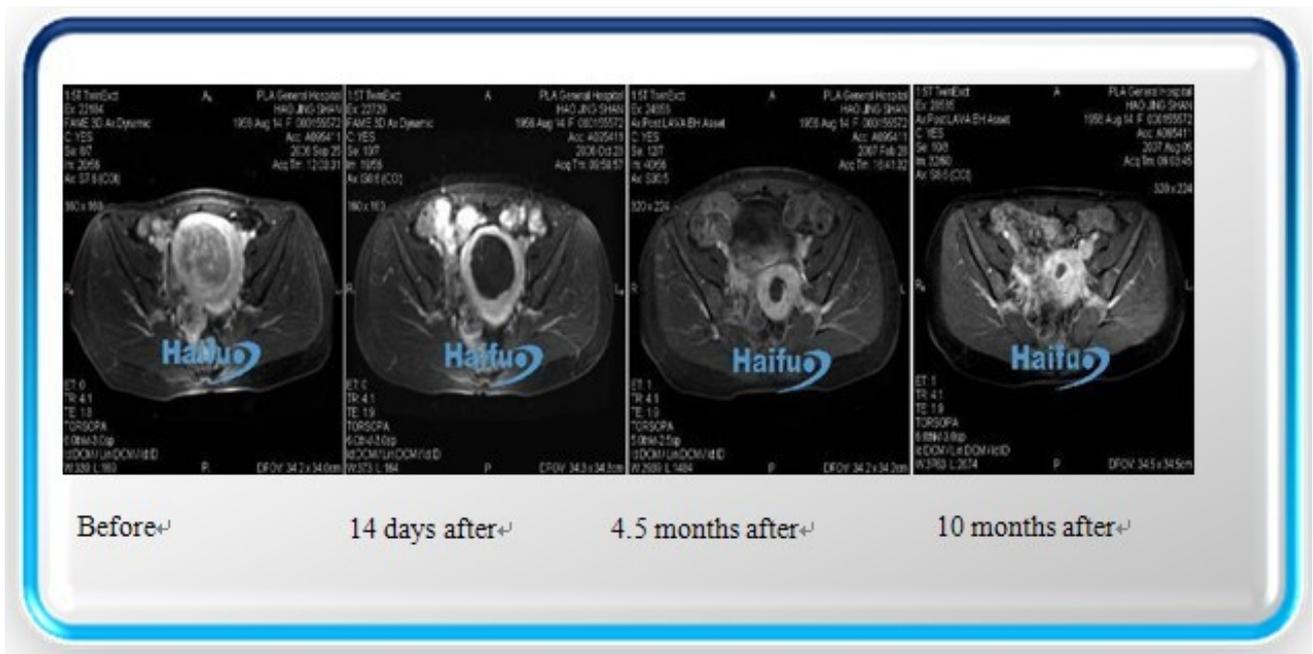


## Patienteninformation

### HAIFU-Therapy for Myomas and Adenomyosis

Ultrasound-guided High Intensity Focused Ultrasound



## **Dear patient,**

One of the first HAIFU systems in the German-speaking space is installed in the institute of diagnostic and interventional radiology of the university hospital Frankfurt.

During the last years it was reported more and more about the application of the HAIFU therapy with a huge number of illnesses. The treatment of good-natured and evil tumor illnesses is in the foreground.

Thus also myomas (good-natured rank growth of the womb musculature) and the Adenomyosis (Endometriosis of the womb) are possible operational areas of the HAIFU-Therapy.

In the following it is more exactly entered on the illnesses and the special therapy possibility HAIFU.

## **Myomas**

### What are myomas?

The so-called Myomas are the most frequent good-natured tumors of the womb and exist of aggregations of uterine muscle cells.

Myomas are localised in the womb at the most different places and they are divided according to localisation into different types.

The exactly causes of the myome development are not known up to now. However, they grow under the stimulus of the female gender hormone estrogen, this is why they are observed almost exclusively with women at the fertile age.

However, in addition to the hormonal influence, genetic factors also seem to play a role with the myoma development.

Myomas are very frequent, they are found with at least 25% of all women at the fertile age.

### Myomas release discomfort

Myomas cause only in approx. 15% of the cases discomfort and symptoms, therefore there are many women who know nothing from their myomas. The Myome diagnostic finding is often raised by chance with gynaecological investigations.

Menstrual disturbances or irregular strong or long persistent monthly periods can be released by big or unfavourably localised myomas. Also Myomas can cause abdominal pains or a pressure feeling. They can lead by pressure on the bladder to reinforced urge to pass water or urinary incontinence. Also they can release pains with the sexual intercourse. Seldom Myomas can be the reason for an undesirable childwish or also for apremature birth or miscarriage.

## Myome Treatment

A treatment of the Myomas is only necessary from medical view if they cause discomfort. With symptom appearance there are different therapy possibilities.

### Operation

The operation is the standard treatment of a myome. There are different accesses: (normal) open operation, belly reflexion, by the scabbard (=trans-vaginal).

On this occasion, either the myome from the womb is got out (Myomektomie), or the whole womb is got out (Hysterektomie).

The complete surgical womb distance is often indicated with very big or numerous myomas. With the Hysterektomie a hospitalisation of 3 to 10 days is necessary, depending on the isolated case. Afterwards a recreational time from up to 6 weeks should be kept.

With the Myomektomie, the pure distance of myomes, the hospitalisation mostly lasts from 1 to 3 days, with especially big Myomas up to one week. The next recreational time amounts on an average up to four weeks.

### Non-operative Treatments

#### Hormone therapy

Because the hormonal influence of estrogen on the myomgrowth is of essential meaning, it can be tried to restrain medicamental the growth, or to achieve a Myom shrivelling. This can happen by the gift of anti-estrogens /Gestagenen.

If one sets down the hormones, nevertheless the myome grows again.

The hormone therapy is no lasting one. It is only a temporary treatment (of many months).

#### Myomembolisation

With the myomembolisation the substantive blood vessels are blocked artificially.

This alternative to operation occurs in local numbing about the strip. Over here a thin catheter is introduced in the vascular system which injects the so-called embolisationmaterial, mostly small plastic globules, locally in the myome.

Consequently the myome blood care is cut off by the resultant vascular fastener (Embolisation). The myome dies and shrinks in following months.

With the myoembolisation a from 1 to 2-day stationary stay becomes mostly necessary. The recreational time after the intervention lasts up to 2 weeks.

## Focused Ultrasound

A new and very careful therapy possibility of myomas is the highly intensive focused ultrasound, shortened HIFU.

Ultrasound calls high frequently oscillations which lie above the human hearing threshold.

For diagnostic purposes the ultrasound is used quite for decades.

Nevertheless, with the HIFU substantially higher energy is generated in contrast to the diagnostic ultrasound.

This functions by the grouping of the rays by special converters which focus the rays on few millimetres of measuring area. (the same effect like with sunrays bundling up magnifying glass)

If the ultrasonic rays are focused now on the myoma tissue, this leads at the aim to create high temperatures which leads to the decease of the myoma cells.

The myome shrinks. The aim guidance of the rays occurs also ultrasound steered what allows an lifetime imaging and with it a realtime control of the treatment.

The myometreatment by means of HIFU is carried out outpatiently, a hospitalization is not necessary for it.

The HIFU therapy occurs in contrast to surgical (minimum-invasive) procedures completely without skin cut and operation scar.

On average two hours are required for the treatment, up to 6 hours, in special cases.

The intervention should take place without general anaesthetic, however, the patient gets painkiller and tranquilizer under sequential supervision by the anaesthesia.

The dismissal from the clinic mostly occurs on the day of treatment after a quiescence of from four to six hours.

The next day an unlimited everyday guidance is possible.

# **Adenomyosis**

## What is the Adenomyosis?

An other good-natured womb illness which often runs very pain-intensely and chronically shows the Adenomyosis.

The clinical picture encloses a waxing womb mucous membrane scattered in the uterine musculature.

Ordinarily a medicamental therapy is tried first.

## Adenomyose-possibilities of treatment

With therapy resistance and persistent discomfort, a full womb distance can come up (Hysterektomie). This operation is carried out in general anaesthetic and requires a stationary hospitalisation.

However, HAIFU sets up as a newer, third therapy form.

The HAIFU treatment is carried out like the Myoma treatment and was already described.

## **Who is suitable for a HIFU treatment?**

The feasibility of a HIFU therapy with adenomyosis or myomas depends on different factors.

First a careful elevation of the gynaecological prehistory and a physical investigation is necessary. Furthermore an imaging of the illness is necessary, for this a MRT investigation of the washbasin with contrast medium is carried out.

By the imaging the recognizable size and the number of the myomas or the changes by the adenomyosis are shown.

For a successful myoma treatment, their number 6 should not excel and the myoma diameter shouldn't cross optimum-wise 10 cm.

However, the therapy decision is made individually, after the patient's case becomes viewed in the common Myoma conference by the gynecologists and radiologists.

## **How is the treatment going on?**

Preparatory measures are inalienable for a successful treatment. It is important that the day before an intestinal preparation occurs to reduce, e.g. intestinal air.

For this you receive a purge and three litres of liquid. You must take the purge the day before about 14 o'clock and drink in addition 1 litre of laxative liquid within one hour.

You drink the second one and the third litre again within one hour at 16 o'clock and 18 o'clock.

From midnight you drink nothing more and on the day of treatment in the morning a

catheter is laid. The skin of the belly wall is cleaned immediately before the therapy, in addition, it is shaved, degreased and degased.

Coagulation-restraining drugs (e.g. Marcumar, Xarelto, Plavix, aspirin) must be set down seven days before the HIFU treatment after an arrangement with all involved doctors.

Also twelve hours of sobriety before the therapy must be kept, this means no food, drinking or smoking

The taking from regularly taken drugs should only be continued after consultation with the doctors.

## **Treatment**

The real treatment occurs for you in face-down situation on a special patient's table. The ultrasonic unity, about which the intervention is steered and which generates the focused rays, is located under the table.

A central computer, directly beside the investigation unity, supervises and steers all devices of the treatment. The treating doctors stand by the central computer, so that a conversation is possible any time.

At the beginning of the treatment you receive a tranquilizer.

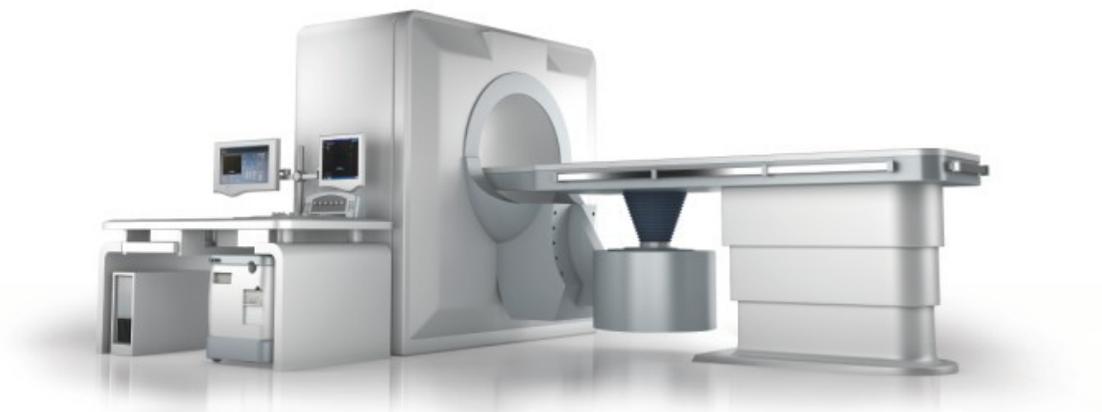
If you suffer during the therapy from pains or you feel poorly, please don't hesitate to inform us.

In particular if you feel pains which emit in the legs, it is very important to announce this immediately to us to prevent a nervous damage.

Now and then a light warming of the skin on the belly is noticed, or a short sting is felt when the ultrasonic impulse is sent.

Many small single steps are passed within one HIFU treatment.

During the treatment the doctors pursue most exactly with ultrasonic pictures the changes and thus steer straight the intervention.



Picture of the therapeutic HIFU-System

## **Aftercare**

After the Treatment you are at first observed in a rest space for at least 2 hours. Tiredness, low blood pressure, abdominal or back pains, fever or dissolution outflow count to the possible side effects appearing at short notice.

Normally you can leave the clinic, nevertheless, after a rest period of from 4 to 6 hours and return the next day to your usual every day life.

In the first month after the treatment you should renounce sexual intercourse.

The success of the treatment can only be ascertained after weeks, because the myoma tissue must recede first. The reduction of myoma is with successful treatment between 1 and 3 cm per month. The myome shrinks after the treatment further.

The maximum shrivelling effect is observed between the 3rd and 6th month after the HAIFU therapy.

Ultrasound and MRT controls in agreed time intervals are necessary for the successful judgement of the therapy.

## **Advantages,disadvantages,side effects**

### Advantages

The HIFU therapy is a very careful, non-invasive form of treatment and poor in complication.

It is not carried out in general anaesthetic and without any surgical measures, loss of blood or postal-surgical stress for the female body.

No ray load originates for you, because merely ultrasound waves are applied.

Besides, your skin is also spared, the ultrasound works only in the depth of the tissue.

The treatment occurs out patiently and permits a quick return in the normal everyday life.

### Child wish

The womb and also the womb neck will be conserved with the HAIFU therapy completely. The fertility is not affected by the HAIFU therapy. A pregnancy is possible furthermore, and many pregnancies have already occurred after a HIFU treatment.

Indeed, a pregnancy should be avoided during the first 6 months after the treatment.

Discuss if necessary please with your gynecologist the prevention methods, which fit for you for this period

## Disadvantages of the treatment/ restrictions of the success of treatment

Normally the treatment by HAIFU causes a considerable reduction of the threatened myome, or a relief of caused pains.

With enormously unfavorable localisation of the myome-or Adenomyosis tissue ,like e.g. in the rear womb wall, immediately neighbouring to intestinal shares and nerves, the complete aim region is not grasped now and then with the treatment.

Nevertheless, a partial treatment ordinarily causes also a favorable effect on the symptoms, nevertheless, this can be very different individually. In the non-treated, normal" womb occasional myome-or Adenomyosis neoplasm is possible.

## Side effects

The HAIFU therapy is a method poor in risk of the non-invasive treatment of myomas and adenomyosis.

Serious side effects are comparatively very rare.

Most often patients notice indisposition. Also beside pains in back and legs, patients report an increased, or painful monthly period during the first three postal-treatment months.

Ordinarily usual painkillers, availble without prescription, suffice to control the pains. Temporarily the treatment can lead to degraded blood pressure, dizziness or feeling of sickness. Light skin phenomena like skin warming or in extremely rare cases skin redness and combustion, like a sunburn, can appear.

## **Who takes over the costs of the treatment?**

Because it concerns a new procedure, the HAIFU therapy (still) does not belong to the standard achievements of the legal health insurance schemes.

With interest in a HAIFU treatment you should turn to your health insurance scheme and apply for an assumption of costs which is granted by some health insurances.

Nevertheless currently it still concerns single decisions.

With these „administrative matters" we help you with pleasure.

If you are insured privately, the medical costs are completely carried by your insurer, or are subsidised at the request. Whether your aid place also takes overcosts proportionately, you would have to clear in the approach directly.

## **Contact**