

Please completed with printed letters.

Name:

Mother's name:

Date of birth:

SSN:

## Information and consent form on cardiac-CT scanning

### — Dear Patients,

Please read carefully all the information on the process of the examination, your tasks, and the possible adverse effects.

### — General information

The cardiac-CT (computer tomography) scanning is a modern imaging diagnostic examination method which allows for the exact determination of the state of the coronary arteries supplying the heart, its path, the location of congestions due to arteriosclerosis, their location and composition. During the examination, X-ray penetrates the chest which is processed by a computer using a detector. As a result, cross section images are obtained which can be processed in any plane. Assessable images from the coronaries can be obtained with the application of intravenous contrast agent. The procedure involves radiation load and injection of intravenous contrast agent; however, you were sent to CT scan by your physician because from your point of view the information obtained this way is more important than the risk of radiation load and that of the injection of the intravenous contrast agent.

During pregnancy, the radiation exposure is to be avoided, the advantage of the application of X-ray examinations with or without contrast agent is to be carefully balanced against the possible risk. During pregnancy, injection of venous contrast agent is especially not recommended for CT scan unless the advantage resulting from its application exceeds the possible risks which is carefully assessed by the referrer and the radiologist conducting the examination. Beyond the avoidance of radiation, the iodine sensitivity of the fetal thyroid gland is to be considered when evaluating the possible risk/benefit assessment.

The contrast agents are secreted into the breast milk in small quantity and are absorbed from the intestines in minimal quantities. If the breastfeeding mother receives contrast agents containing iodine, the breastfeeding can be continued as per normal conditions.

### — Examination procedure

The full duration of the cardiac-CT scans (following possible preparation) is typically 30 minutes. After the contrast agent examination, you have to stay in the waiting room for 20 minutes to allow for the recognition of the possible side effects of the contrast agent and, if necessary, to commence the appropriate medication.

The examination takes place in lying posture and involves no pain. During scan the arms are to be positioned above the head to avoid generation of artefacts. Please remove any removable metal items (necklace, earrings, hairpin, removable denture, etc.) from the waist up because they also generate artefacts and may render the examination invalid. You must also remove your clothing (from the waist up).

During the cardiac-CT scan intravenous contrast agent is given. This is usually introduced into the body through the brachial vein, usually using a pump (injector). During this you may experience warmth, hotness for a short time. Metallic taste, possibly nausea, rarely vomiting may occur. During the examination the heart function is monitored with EKG.

The examination is supervised by a cardiologist specialist who may recommend taking cardiac frequency reducer medicine prior to the examination if required. During the examination, in order to obtain a more accurate outline of the coronaries, nitroglycerine spray is applied under the tongue, the taste of which may be slightly unpleasant, temporary low blood pressure and dull headache may occur. The medicine discharges from the body in about 10-15 minutes, so the inconvenience caused by it will also disappear.

Do not move during the examination. During scan, breath must be held for time to time, the scan operator will instruct you so via microphone.

### — What to do before cardiac-CT scan

Unless the physician otherwise ordered, do not eat for at least 4 hours before the examination, do not have coffee or other stimulating beverage that day and also do not smoke! Consume ample quantity of non-carbonated drinks!

The prerequisite of a good scan is the stable pulse preferably under 60 BPM. If required, our cardiologist specialist may recommend taking pulse reducer medicine (metoprolol, ivabradin) one hour before the examination. To determine this, present yourself 60 minutes before the time of the examination.

**For the examination it is required to have a renal function laboratory test not older than 30 days and a resting EKG (ECG) test, please bring results of these and any earlier cardiology records with you!**

Please fill out with printed capital letters.

Name:

Mother's name:

### — What to do after cardiac-CT scan

Consume a lot of liquid following the administration of the contrast agent to help the recovery of the liquid balance of the body and the faster excretion of the contrast agent even if you do not need any liquid restriction due to a disease.

### — Possible hazards, adverse effect and their avoidance and prevention

For the administration of iodinated contrast agent required during the CT scanning, the following must be considered in case of patients taking medication for diabetes in case of certain products:

Patients with diabetes taking METFORMIN:

1. **NO CHANGE NEEDED** in the administration of METFORMIN, if
  - they have no acute renal insufficiency,
  - their eGFR value > 30 ml/min /1.73 m<sup>2</sup>
2. **THE TAKING OF METFORMIN-BASED MEDICINE MUST BE SUSPENDED FOR 48 HOURS FOLLOWING THE ADMINISTRATION OF THE CONTRAST AGENT**, then it may be resumed afterwards only if the control eGFR value has not changed significantly in case of patients who
  - have no acute renal insufficiency and the eGFR value < 30 ml/min /1.73 m<sup>2</sup>

Please check if you are taking diabetes medicinal product containing metformin, if yes, then consult with your physician on the method of its administration! With normal kidney function, the contrast agent will not damage the kidney, but it is **IMPORTANT** to consume ample amount of liquid (min. 1.5-2 litres!) in the days before and after the contrast agent CT scanning.

In case of contrast agent CT scans the contrast agent is usually introduced into the body through the cephalic vein, usually using a pump (injector). You may feel warmth, hot sensation for a short time during injection. Metallic taste, possibly nausea, rarely vomiting may occur. In case of those prone to it, the contrast agent may exit from the blood vessels, causing a stretching, stinging sensation. Should such sensation occur, please notify us! This does not cause any damage, absorbs without trace. The bandaging of the limb is recommended.

The contrast agent is a chemical compound containing iodine which is suitable for outlining the blood vessels and the examination of the circulation of organs and tissues. The contrast agent, as any other medicine, may trigger hypersensitivity. The hypersensitivity may occur not only due to the iodine itself but to the complex of the iodine and the molecule attached to it, that is, the compound. Contrast agent hypersensitivity (allergy) occurs rarely. Symptoms: swelling of face, lips, tongue, throat, coughing, itching, nose running, sneezing, urticaria, dyspnoea, sensation of suffocation. Should these or other symptoms occur after the administration of the contrast agent, immediately notify the examining operator. Be advised that these symptoms may occur later, within 24 hours, in such case please report to your attending physician or at the emergency ward! In most cases the allergy is mild, severe allergy is rare. It is extremely rare to have anaphylactic (hypersensitivity) shock state which, in extreme cases, may lead to circulatory collapse and cardiac arrest. Our institute is equipped and prepared to prevent a possible allergic reaction, the necessary clinical background is available.

Should you have any further questions, ask the medical personnel performing the examination or the specialist controlling the examination.

As for any diagnostic examination, the cardiac-CT scanning and the contrast agent cardiac-CT scanning also require that you give your consent if you request to have them performed according to the law on health. Without your signature on the informed consent the examination cannot be performed.

— **Thank you for your cooperation, we wish you good health.**

## Examination questionnaire

Please answer the questions below, marking your answer with an X using the check box.

**Are you pregnant or is it possible that you are pregnant?**  Yes/ It is possible  No

Please note that if the answer is Yes/It is possible, you have to fill out the relevant pregnancy questionnaire & consent form before undergoing an examination that involves radiation.

Please completed with printed letters.

Name:

Mother's name:

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| Are you aware of having/ do you have hypersensitivity to any kind of medicine?                       | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Have you ever been administered contrast medium during a CT, angiography (DSA) or X-ray examination? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| If yes, did you have any kind of allergic symptoms?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have asthma?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have hypertension (high blood pressure)?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have diabetes?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have gout?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have any kind of untreated thyroid disease?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have any kind of kidney disease (previous kidney surgery, proteinuria)?                       | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have a contagious disease (tuberculosis, hepatitis, etc.)?                                    | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Are you currently breastfeeding?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have any other significant diseases?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Other significant disease

Height (cm)

Body weight (kg)

## Consent form

I, the undersigned, hereby declare that I have been fully informed both in written and verbal form, especially about the nature, purpose and steps of the procedure in a way that I can understand. I have also been informed about the possible complications, benefits and risks of a missed examination, and my rights about consenting to the examinations and interventions.

I was given the opportunity to ask further questions, my questions about the procedure (if I had any) were answered to my satisfaction, and I understand what was said. I was given the opportunity to learn the name, qualification and position of the personnel directly involved in the procedure. I have no further questions and I do not need further time to think. I have been given sufficient time to make my decision and I give my consent under no duress and of sound mind.

**I understand the nature of the examination and agree to the cardiac-CT scanning.**

Signature of the patient (or legal representative)

I have been informed that for evaluable results sometimes it may be necessary to administer contrast medium. I acknowledge that if I reject the administration of the contrast medium, the images might be less informative, and this may result in adverse consequences, for which Affidea is not liable.

I agree to the administration of intravenous contrast medium if necessary.

No, I do not agree to the administration of intravenous contrast medium.

Signature of the patient (or legal representative)

Please completed with printed letters.

Name:

Mother's name:

**If the PATIENT CANNOT MAKE A STATEMENT and/or sign on their own behalf, the reason for this**

- Minor (under the age of 18)
- Vulnerable adult (diminished capacity/incapacitated)
- Other - please specify

**Full name of legal representative**  
**(Please completed with printed letters.)**

**Date of signing the statement**