Declaration of consent

for **cardiac catheterisation and treatment of narrowed (stenotic) or occluded coronary vessels** (balloon dilatation and similar interventions)

Patient name	Patient date of birth

Examination and treatment procedure
The following explanations are intended to inform you on the above mentioned medical intervention. They are intended to enable you, within the scope of your right of self-determination, to weigh the advantages and disadvantages and decide for or against this intervention.

Coronary angiography (imaging of the coronary vessels for diagnosis): A local anaesthetic is first applied to the skin for access through the arm or groin artery. The coronary vessels are then visualised via a catheter using contrast medium under X-ray fluoroscopy. In certain situations, blood flow (flow reserve) is measured using microsensors or detailed images are taken (e.g. intravascular ultrasound IVUS). **Right heart catheter:** If the pressure conditions in the pulmonary circulation need to be examined, access occurs via a vein and the pressure in the heart is measured with a catheter.

Coronary intervention (treatment of narrowed (stenotic) vessels with balloon/stent): In the case of relevant stenoses in the coronary vessels, these stenoses can often be treated directly after the examination by balloon dilatation and/or insertion of a stent (metal mesh). Subsequently, it is likely that medication will have to be taken to prevent the formation of blood clots at the inserted stent.

Benefits
Coronary angiography or right heart catheterization provide important information for optimal therapy. In the case of sudden narrowing/occlusion of a coronary vessel, coronary intervention can restore blood flow to normal and be life-saving. In the case of chronic narrowing, it can also improve symptoms.

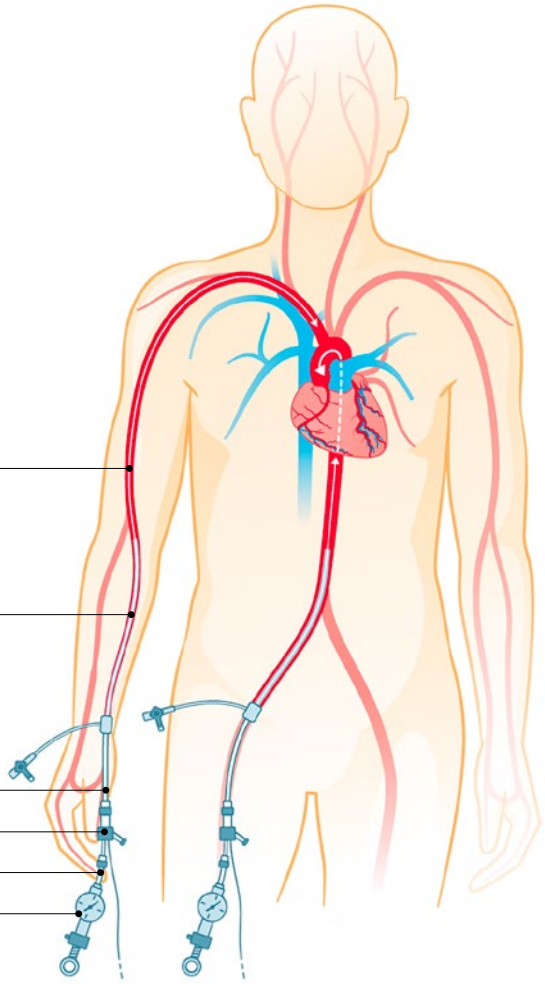
Possible risks and complications
Rare but potentially serious
(< 1 per 100–1000 patients):
- vascular injury/internal bleeding (possible treatment: stent, pericard puncture, surgical intervention)
- cardiac arrhythmia (possible treatment: defibrillation)
- clot formation/embolisms (impaired heart circulation, stroke), allergic reaction, death

More frequent but usually unproblematic
(< 5 per 100 patients):
- bleeding at the puncture site (usually unproblematic; at worst blood transfusion and/or surgical intervention may be required)
- vascular occlusion at puncture site, kidney problems

Other complications are possible but very rare. However, the risks may vary depending on the situation and patient's state of health (emergency intervention, type of stenosis).

Alternative methods

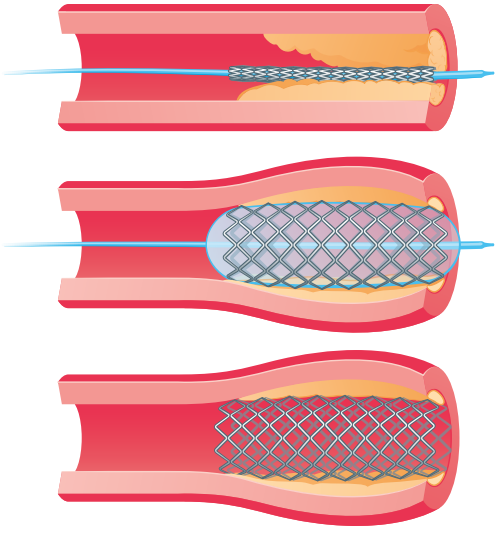
Instead of coronary angiography, other imaging methods are possible in certain cases (CT, MRI, etc), but these do not allow direct treatment. Instead of balloon dilatation, surgical bypass surgery or just drug therapy may be possible.



The folded stent mounted on the balloon catheter is advanced into the stenosis of the coronary artery via a fine wire.

The balloon is expanded with fluid and the stent is implanted into the coronary artery at the same time as the stenosis is widened.

After deflation of the balloon, the balloon catheter and wire are removed. Successful stent placement ensures the free flow of blood.



Declaration of consent to the transfer of data to the SwissCaRe quality registry.

Please read the separate patient information on the SwissCaRe quality registry.

I agree that personal data relating to my procedure, including my name, sex and date of birth, is collected for quality assurance and transmitted to the national quality registry SwissCaRe. The registry is managed on secure servers at the University of Bern (SwissRDL). I have been informed of the scope and purpose of the data transmission by means of the patient information on the SwissCaRe quality registry, version 1/2022. Any questions I had were answered. It was explained to me that my decision whether or not to consent to the data transfer to the registry has no influence on my treatment. I know that I can revoke this consent at any time, without giving reasons.

☐ **YES**, I agree that my personal data will be transmitted to SwissCaRe

☐ **NO**, I do not want my personal data to be transmitted

Further comments

Please talk to us
if there is anything you have not understood or if something seems important to you that was not mentioned in this document or in the personal conversation with your doctor.

Consent to the intervention
I have been fully informed on the purpose, risks as well as alternative treatment methods, I have understood the explanations and have been able to ask the questions I am interested in. I agree with the planned procedure, and also with the discussed changes and extensions that may prove necessary during the procedure.

I have been informed about the planned intervention by the physician and agree to it.

Physician name

Signature patient

Signature physician

Place/date

Place/date

Schweizerische Gesellschaft für Kardiologie
Société Suisse de Cardiologie
Società Svizzera di Cardiologia

Schweizerische Herzstiftung
Fondation Suisse de Cardiologie
Fondazione Svizzera di Cardiologia

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