

TRANSCATHETER INTERATRIAL SEPTAL DEFECT CLOSURE (PFO/ASD) KATHETER-VERSCHLUSS EINES DEFEKTES IN DER VORHOFSCHEIDEWAND (PFO/ASD)

Information and medical history for patients for preparation of the required pre-procedure interview with the doctor

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

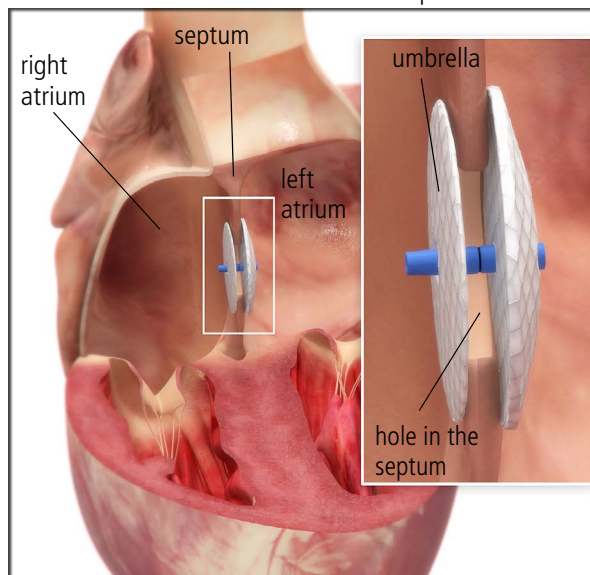
Dear patient, dear parents,

you have/your child has been diagnosed with an atrial septal defect (ASD) or a patent foramen ovale (PFO), meaning a hole in the wall separating the two atria of the heart. These are among the most common congenital heart defects. By closing the hole in a catheter procedure, symptoms are to be alleviated or complications prevented.

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

CAUSES OF INTERATRIAL SEPTAL DEFECT

There is a natural connection between the left and right atrium while the child is developing inside the womb. After birth, this connection is normally closed once breathing through the lungs commences. However, in about one fourth of all human beings, it does not close fully. This "patent foramen ovale" (PFO) usually does not cause any problems since blood can only pass through it if the pressure in the chest is increased, for instance during coughing or pressing. However, if small blood clots travel from the venous to the arterial circulatory system via this opening, they can end up in the vessels supplying the brain and thus cause a stroke. A closure of the PFO is meant to prevent this.

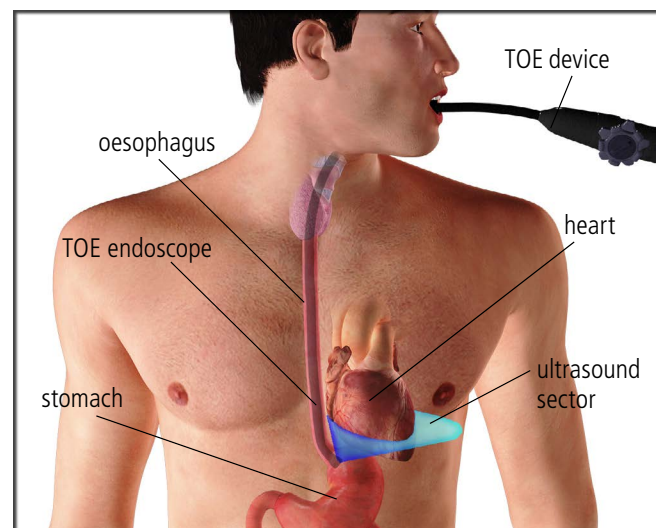


Larger interatrial septal defects (atrial septal defect [ASD]), however, result in constant passing of blood from the left into the right atrium. The right atrium and, consequently, the right cardiac

chamber then have to deal with a larger amount of blood than normal. The right atrium, the right cardiac chamber and the lung arteries then become enlarged as a result. In order to prevent this, defects of a certain size should be closed.

Many defects can be cured nowadays using heart catheter treatment, which puts little strain on the patient. Whether or not this will be possible depends on the size and location of the defect.

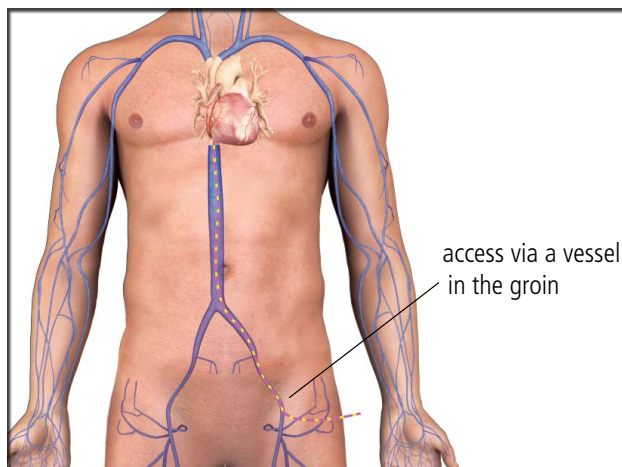
COURSE OF PROCEDURE



Heart catheter treatment is usually carried out under a local anaesthetic. You/your child may also have a sedative or sleep-inducing drug administered if needed. In younger children, the procedure is usually carried out under general anaesthesia, regarding which you will receive a separate information sheet. In order to prevent formation of blood clots during the procedure, you may have an anticoagulant agent administered to you.

During the procedure, the defect will be made visible using an ultrasound probe from the outside or from the oesophagus. Prior to ultrasound imaging via the oesophagus, so-called transoesophageal echocardiography (TOE), the throat will be anaesthetised locally with a spray. As with a gastroscopy, a tube-like device with an ultrasound transducer at its tip is then inserted through the mouth into the oesophagus right up to the stomach. From there, the heart can be examined very closely via the ultrasound. In order to be able to see the heart's structures more clearly, an ultrasound contrast medium may be administered via a vein in addition in some cases.

The doctor will then puncture a suitable vein, rarely an artery, in the groin. A flexible plastic tube (catheter) is then moved all the way into the heart through the pelvic and abdominal vessels. An inflatable balloon may be used to measure the size of the hole in the septum. Then, a folded-up double-umbrella device is moved through the catheter into the defect and unfolded there in order to close the hole.



After the procedure, the catheter is removed, pressure is applied to the access in the groin and the puncture site is treated with a dressing.

ALTERNATIVE METHODS

In some cases, the defect is so small, it only puts little strain on the heart and lungs. A closure may then be reconsidered or postponed.

If the septal defect is too large or too close to a heart valve or the main artery (aorta), the defect will have to be closed in open surgery. Minimally invasive procedures have become available for this in the meantime, which only require a small incision on one side of the chest.

Patients with stroke or other embolisms may have to take anticoagulant agents permanently in addition to the PFO being closed. Your doctor will explain to you why he would recommend transcatheter interatrial septal defect closure in your particular case/your child's case.

PROSPECTS OF SUCCESS

Closing the defect with the umbrella is usually successful, resulting in permanent and secure closure of the defect. However, in some instances, this will not be successful, and the defect or an incomplete closure will then have to be remedied in a second procedure or in open surgery.

Since this procedure has only been available for about 20 years, no final statements can be made at this stage regarding long-term results or late complications exceeding that period of time.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: It is important to inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Plavix®, Eliquis®, Xarelto®, Pradaxa® etc.) or have taken irregularly over the course of the past eight days prior to the procedure. This includes any over-the-counter medication and herbal remedies. Your doctor will let you know which medication should be stopped for which period of time.

Food, drink and smoking: Please stop smoking at least one day prior to the scheduled procedure. As a general rule, you may not eat anything any more 6-8 hours prior to the procedure and not drink any juices with pulp, milk, broth or alcohol. You may imbibe clear fluids such as water or tea without milk or cream up until approx. 2 hours prior to the procedure.

Aftercare:

Please do not get up on your own after the procedure, as requested. In order to avoid post-procedure bleeding, **several hours of bed rest** are usually required.

Should you notice any **bleeding** at the puncture site, please apply pressure to the affected area and immediately inform the nursing personnel or the doctor.

Excessive strain, heavy lifting or strong pressing should also be avoided for several days after the procedure to avoid **post-procedure bleeding**.

Since the umbrella will take approx. six months until it is fully grown in, **anticoagulant agents** will have to be taken for that period of time in order to prevent blood clot formation. Other medical procedures which can lead to bacteria entering into the bloodstream, such as gastroscopy, also require preventive treatment with antibiotics during that period of time (**endocarditis prophylaxis**).

After the procedure, **check-ups** using ultrasound imaging of the heart via the oesophagus or a chest ultrasound will be required. Please be conscientious in keeping those appointments.

Please inform your doctor immediately or come to the clinic should you experience **bleeding, swelling, pain, intense reddening of the wound or secretion from the puncture site, numbness or paling of the affected leg, pain in your chest, heart problems, shortness of breath, fever or chills**.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. These may sometimes require additional treatment or surgery and can sometimes even be **life-threatening** or lead to permanent damage – even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

Bruising (haematomata) often occurs at or around the puncture sites. This may lead to firm, painful swelling. Most of the time, this will disappear after a few days or weeks even without treatment. If not, surgical removal of the haematoma may become necessary.

The moving forward of the catheter may be accompanied by **cardiac arrhythmia**. This is usually harmless and temporary. Severe cardiac arrhythmia requiring treatment using medication or a power surge (defibrillation) occurs only in very rare cases.

In some cases, the moving forward of the catheter can lead to a **loop** forming. If it cannot be undone successfully, the catheter will have to be surgically removed.

The moving forward of the catheter can result in **tears in the internal wall of a vessel (dissection)** accompanied by bleeding and constriction of the vessel or **complete obstruction of the vessel**. The wall of the heart or a heart valve may also be injured in rare cases. In such events, surgery may be required. If **bleeding into the pericardial sac** (pericardial effusion) occurs as a result of the wall of the heart being injured, it will have to be punctured immediately.

Under very unfortunate circumstances, the umbrella may become loose if it was not fixed properly and start travelling, leading to **obstruction of a vessel**. If the umbrella cannot be removed via a catheter, it may have to be removed in a surgical procedure.

In some cases, the blood vessel will not close up properly at the puncture site, resulting in an **aneurysm of the vessel** (pseudo-aneurysm). This can normally be treated effectively by applying a compression dressing or through an injection into the aneurysm (sclerotherapy). In some cases, surgery may become necessary.

In rare cases, a connection will form between the artery and the vein (**fistula**), which will usually have to be closed surgically.

Damage to the skin, soft tissue or nerves - for instance through the puncturing, bruising, syringe abscess, disinfectants, a compression dressing or despite proper positioning - may occur. Numbness, paralysis and pain may then result. They are usually temporary. On rare occasions, these symptoms may persist even after treatment, or scars may remain.

Since during the catheter procedure, anticoagulant agents may have to be administered, the risk of (**post-procedure**) **bleeding**, particularly at the puncture site, but also in other areas of the body will be increased. In extreme cases, bleeding in the brain may occur, which can result in speech problems or paralyses. If Heparin is administered, it may lead to a severe immune response (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

Should **severe blood loss** occur, the use of donor blood/blood components (**transfusion**) may be required in exceptional cases. This can lead to **transmission of diseases**, albeit in very rare cases, such as hepatitis (causing dangerous inflammation of the liver), HIV in extremely rare cases (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other dangerous – even unknown – diseases. Donation of your own blood usually isn't useful.

Existing blood clots (**thromboses**) may become detached through the moving forward of the catheter and cause obstruction of a blood vessel (**embolism**). Blood clots can also form anew or travel to other organs, leading to blood vessel blockages there. Even despite immediate treatment, this may lead to permanent damage to the affected organ (e. g. **lung embolism**, **stroke** including permanent paralyses, **heart attack**).

In rare cases, air may enter into the vein through the catheter (**air embolism**), leading to lung embolism.

Infections, for instance at the puncture site, can usually be treated with antibiotics. Surgical intervention will rarely be needed. In exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia) and even to inflammation of the endocardium (endocarditis), an **infection of the umbrella** may lead to **pericarditis**. Adequate intensive care will then be required.

Allergic reactions, for instance to medication or latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reaction such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralyses or kidney failure requiring dialysis.

Trouble breathing or circulatory problems, for instance as side effects of administered sedatives, can usually be treated effectively by administering oxygen or medication. Artificial respiration will only be necessary on rare occasions.

Impaired blood circulation in the patient's leg may occur if the punctured blood vessel was injured or has become blocked by a blood clot after the procedure. In exceptional cases, this may result in a loss of function of the affected leg, in extreme cases it may result in the patient losing the affected leg.

Sometimes **lymphatic obstruction** will lead to permanent swelling of the punctured leg.

In individual cases, X-ray using contrast media may become necessary during the procedure to make blood vessels visible. If a contrast medium is administered, patients already suffering from kidney disease may experience a **decrease in kidney function**. However, this can usually be treated by increasing one's intake of fluids or administering medication. If the kidneys were already severely damaged, a patient may suffer **kidney failure**, leading to permanent dialysis possibly becoming necessary. Diabetics who are on biguanides such as Metformin may experience dangerous **disturbances of the metabolism** (acidosis).

Patients with dysfunction of the thyroid gland may experience **hyperfunction of the thyroid**, so-called hyperthyreosis, due to the use of iodine-containing contrast media. This will lead to tachycardia, hot flushes, restlessness and diarrhoea, but can be easily treated with medication.

Radiation exposure through the X-ray guidance which may be required will be kept as low as possible. However, reliable data regarding the long-term effects is currently not available. If a patient is pregnant, radiation may cause damage to the unborn child.

Special risks involved in ultrasound examination of the heart via the oesophagus (TOE)

Injuries of the oesophagus, the larynx or the **windpipe** usually do not occur unless the patient already had problems swallowing, constrictions, varicose veins or aneurysms into the oesophagus. Any **bleeding, hoarseness** or **problems swallowing** usually disappear again without treatment. A **puncturing** of the oesophagus is extremely rare and may require surgery if it occurs.

When the TOE endoscope is withdrawn, **mucus** from the oesophagus may be moved upward and can then be **inhaled into the windpipe**. In most cases, simply removing the endoscope will suffice in order for the patient to be able to cough up the mucus.

The administration of ultrasound contrast media may lead to temporary **headaches, dizziness, taste** or **sensory disturbances** such as tingling and numbness. A drop in blood pressure rarely occurs, very rarely even a **loss of consciousness**.

Tooth damage may sometimes occur. If teeth are loose, one or more may fall out.

Over the course of several weeks, **cardiac arrhythmia** may occur, which may then have to be treated with medication.

Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

Do you take any diabetes medications? yes no

insulin injections, drugs containing metformin (e.g. Glucophage®, Metformin®, Janumet®).

Werden Diabetesmedikamente eingenommen?
 Spritzen (Insulin), metforminhaltige Tabletten.

Any other: _____
Sonstiges:

Information about medications:

Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? yes no

Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efient®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efient®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Any other: _____
Sonstiges:

When did you take the last dose? _____
Wann war die letzte Einnahme?

Do you take any other medications? yes no

Werden andere Medikamente eingenommen?

If so, which ones: _____
Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Have you ever had a cardiac catheterisation? yes no

Wurde schon einmal eine Herzkatheteruntersuchung durchgeführt?

If so, when? _____
Wenn ja, wann?

Were there any complications? yes no

Ergaben sich dabei Komplikationen?

If so, which ones? _____
Wenn ja, welche?

Have you ever received contrast medium? yes no

Haben Sie schon einmal Kontrastmittel erhalten?

Were there any complications? yes no
Ergaben sich dabei Komplikationen?

If so, which ones? _____
Wenn ja, welche?

Have you ever received a blood transfusion? yes no

Haben Sie schon einmal eine Bluttransfusion erhalten?

Were there any complications? yes no

Ergaben sich dabei Komplikationen?

If so, which ones? _____
Wenn ja, welche?

Are you pregnant? not certain yes no Sind Sie schwanger? nicht sicher

Do you have or have you ever had any of the following diseases: Liegen oder lagen nachstehende Erkrankungen vor:

Blood diseases / blood clotting disorders? yes no

Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), tendency to bruise (frequent bruising possibly for no particular reason).

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

Do you have any blood relatives with signs of blood disease / clotting disorders? yes no

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

Blood clot (thrombus) / blood vessel occlusion (embolism)? yes no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons), pollen (grass, trees), anaesthetics, metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

Allergie/Überempfindlichkeit? Medikamente, Lebensmittel, Kontrastmittel, Jod, Pflaster, Latex (z.B. Gummihandschuhe, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Any other: _____
Sonstiges:

Heart, circulatory or blood vessel diseases? yes no

Heart attack, chest pain and/or tightness (angina pectoris), heart defect, irregular heart rhythm, inflammation of heart muscle, heart valve disease, shortness of breath while climbing stairs, heart surgery (possibly with insertion of an artificial heart valve, pacemaker, defibrillator), high blood pressure, low blood pressure, stroke, varicose veins, inflammation of a vein, thrombosis, embolism.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhythmusstörungen, Herzmuskelenzündung, Herzklappenerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Thrombose, Embolie.

Any other: _____
Sonstiges:

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
Sonstiges:

(If certain answers are preselected, please correct them if anything has changed.)

Thyroid diseases? yes no

Underactive thyroid, Overactive thyroid, Basedow disease, Nodes, Thyroid swelling (goitre).
Schilddrüsenerkrankungen? Unterfunktion, Überfunktion, Basedowsche Krankheit, Knoten, Kropf.

Any other: _____
 Sonstiges:

Kidney diseases? yes no

kidney insufficiency, kidney inflammation.
Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung.

Any other: _____
 Sonstiges:

Communicable (contagious) diseases? yes no

Hepatitis, tuberculosis, HIV.
Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____
 Sonstiges:

Any other acute or chronic diseases / illnesses? yes no**Nicht aufgeführte akute oder chronische Erkrankungen?**

Please describe: _____
 Bitte kurz beschreiben:
