

REMOVAL OF THE GALL BLADDER (CHOLECYSTECTOMY) GALLENBLASENENTFERNUNG (CHOLEZYSTEKTOMIE)

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,

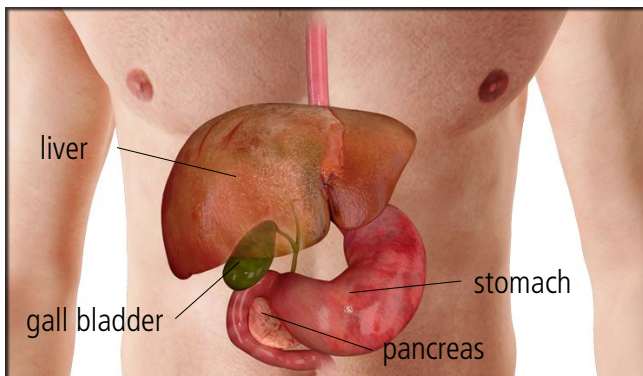
in order to alleviate your symptoms (such as pain in case of gallstones, biliary colic, jaundice, inflammation of the liver, gall bladder or pancreas), the surgical removal of your gall bladder is planned in your case.

The following text is intended to inform you about the course of the operation, related risks and any measures you need to take before and after the procedure as well as 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 and of any potential complications which could result from them. The doctor will answer all of your questions in order to reduce any fears or concerns you may have and to inform you in detail regarding the examination/treatment. You may then consent to the procedure suggested to you or reject the procedure.

Please read the following information and complete the form carefully. It is understood that your data will be treated as confidential. Your doctor will provide you with a copy of the completed and signed form after the interview.

POSITION AND FUNCTION OF THE GALL BLADDER

The gall bladder is situated below the liver. It stores bile produced by the liver and releases it into the colon if needed in order to facilitate the digestion of fats. The loss of your gall bladder won't have any negative effects on your ability to digest, since bile will continue to be produced by the liver and released directly into the colon.



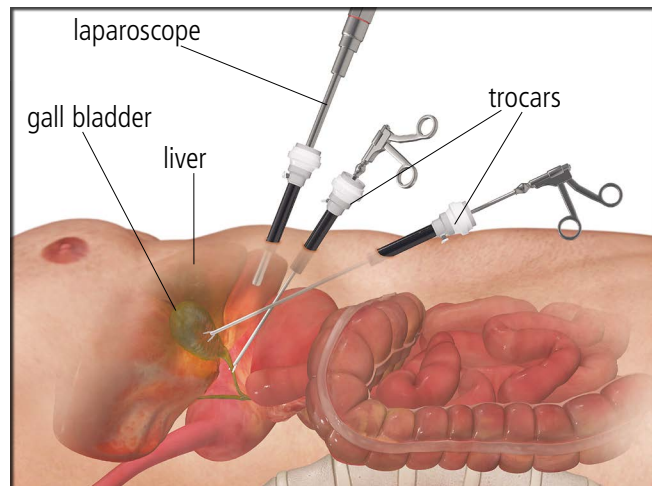
Gallstones can be entirely symptom-free; in that case, you won't need any treatment. However, they may cause problems such as epigastralgia and should then be operated on. When moving through the bile duct, they can cause biliary colic involving extreme pain that comes and goes. A blockage of the bile ducts through a gallstone can lead to bile accumulating, which in turn will lead to jaundice (icterus), inflammation of the bile ducts, gall bladder or the pancreas.

If the gall bladder is inflamed, this may sometimes be accompanied by intense pain and there is a risk of gall bladder rupture.

In these cases, the gall bladder should be removed in order to avoid further complications. A tumour in the gall bladder is another indication for its removal.

COURSE OF OPERATION

The surgical removal of the gall bladder can be carried out in two different ways: via the conventional method involving a larger abdominal incision (often below the right costal arch) or via minimally invasive surgery involving a laparoscopy.



Today, laparoscopy is the standard surgical method used. An incision 1-2 cm in length will be made in the area of the navel and a thin tube (trocar) will be inserted for the laparoscopic camera. Then the abdomen is inflated with carbon dioxide gas and the abdominal area is inspected via a small video camera. Afterwards, 2-3 additional trocars are inserted via further incisions of 5-10 mm. Through these, surgical instruments needed for the operation are inserted.

First of all, the cystic duct and the vessels supplying the gall bladder with blood are identified, exposed and severed with

clips after having been bound off. The blood vessels supplying the liver and the main bile duct have to be carefully protected in the process in order to prevent serious complications. Then, the gall bladder is dissected from the liver bed and is removed from the abdominal cavity via the incision in the navel area using a specimen retrieval bag. If there are large gallstones, a larger incision (2 - 4 cm) may have to be made in order to ensure safe retrieval of the gall bladder. If stones inside the bile duct are suspected, an examination of the bile ducts with contrast media may be required additionally. For this purpose, an X-ray contrast medium is injected into the bile duct and the bile duct is then examined with an X-ray. If there are gallstones inside the bile duct, it can be opened and the stones can be retrieved. However, often the stones will be removed during a cholangiography at a later point in time.

Finally, the surgical area will be rinsed thoroughly and examined for possible sources of bleeding or bile leaks. If need be, a small rubber tube will be inserted as a drain.

POSSIBLE ADDITIONAL MEASURES

In certain cases, it may not be possible to use minimally invasive surgery (for instance in the event of complications, such as severe bleeding or difficult conditions in the surgical area, e.g. adhesions from previous operations, severe inflammation). In this case, open surgery involving a larger abdominal incision will be required.

In some cases, it may be necessary to insert a tube (surgical drain) in order to drain bile from the bile duct through the abdominal wall for an extended period of time after stone removal from the bile duct.

ALTERNATIVE METHODS

If the gall bladder is inflamed, antibiotics can be used as a first step. However, often the inflammation will recur, which will then make surgery necessary. Alternative methods to remove gallstones, such as breaking them up with shock waves, are not promising. Your doctor will explain to you why he would recommend a removal of the gall bladder in your particular case.

PROSPECTS OF SUCCESS

After the removal of your gall bladder, the cause of your symptoms has usually been dealt with. In rare cases, a stricture of the bile duct involving the accumulation of bile or the formation of new stones may occur. This may result in further surgical intervention being required.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please follow the instructions of the doctor and of the nursing personnel closely. 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® [ASA], Marcumar®, Plavix®, Eliquis®, Xarelto®, Pradaxa® etc., and metformin-containing antidiabetic medicines, so-called biguanides) 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 if and for how long you should stop taking your medication.

Aftercare:

Post-surgical pain can usually be alleviated with medication. Shoulder pain may occur as a result of the gas used to inflate the abdomen and the drain and should disappear within a short period of time. The surgical drain is usually removed the day after the operation.

To prevent incisional hernia, please refrain from lifting anything heavier than 5-10 kilos for a period of 3-4 weeks after the oper-

ation. The suture material can either remain or the stitches will be removed after 10-14 days.

You should refrain from eating and drinking for at least 4 hours after surgery. After that period of time, diet progression can commence in accordance with your doctor's instructions.

There is no need to adhere to any particular diet after the removal of the gall bladder, but it is advisable to avoid fatty foods initially.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS SIDE EFFECTS

It is well known that **any surgical procedure**, even a routine procedure such as gall bladder removal, **is accompanied by certain risks**. If complications occur, they may sometimes require additional treatment or surgery and, in extreme cases, 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.

General risks

Allergic reactions (intolerance symptoms), for instance to medication (analgesics, sedatives) or to disinfectants used rarely occur. Skin rash, itching, swelling or nausea and coughing may then occur as a result. They normally disappear without treatment. Severe reactions such as shortness of breath, spasms, tachycardia or circulatory shock are rare. Due to insufficient perfusion, temporary or permanent organ damage, e. g. brain damage, paralysis or kidney failure may occur even despite adequate intensive care.

Post-procedure **bleeding** is usually noticed immediately and can then be stopped. On very rare occasions, postoperative bleeding may occur, requiring an additional surgical intervention at worst. 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, such as hepatitis in very rare cases (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.

Sometimes blood clots (**thromboses**) may form during or after the operation, causing obstruction of a blood vessel. Such blood clots may then travel to other parts of the body and block the vessels of other organs (**embolism**). This may then lead to e.g. lung embolism, stroke or kidney failure resulting in permanent damage despite proper treatment. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, the risk of **severe coagulopathy** (HIT) is increased. This means that the risk of thrombosis formation and thus obstruction of blood vessels is increased.

Infections for instance of the surgical wound or at the site where injection needles were inserted, tissue death (necrosis) and scarring, syringe abscess or vein inflammation (phlebitis) rarely occur. In most cases, infections can be treated successfully with antibiotics. If the gall bladder is inflamed, the risk of infections is increased and an inflammation of the abdominal lining (peritonitis) may occur as well as a build-up of pus, which will then require additional surgery. In rare cases, germs may be introduced into the bloodstream, leading to dangerous blood poisoning (toxaemia) or inflammation of the endocardium (endocarditis) as a result. Adequate intensive care will then be required. In extremely rare cases, an infection may result in the death of a patient despite proper treatment.

Damage to the skin, soft tissue or nerves (e. g. through injections, disinfectants, the use of electrosurgical instruments or despite proper positioning) is rare. Sensory disturbance, numbness, paralysis and pain may then result. They are usually temporary. Permanent nerve damage or scars are rare.

Small nerves in the skin can be severed during surgery and lead to temporary or, in rare cases, even **permanent numbness** around the surgical scar.

With patients predisposed to delayed wound healing or **wound healing disorder**, painful scarring and abnormal proliferation of scar tissue (keloids) may occur. This may require corrective surgery.

Special risks

An **injury of neighbouring organs** such as the liver or colon is rare; injury of the pancreas, spleen, diaphragm or stomach is very rare. If the bile duct has been injured, a blockage of the duct may occur, resulting in jaundice (icterus) or a leakage of bile duct into the abdominal cavity. This may require connecting the bile duct to the small intestine in a separate surgical procedure. Atypical location of blood vessels increases the risk of injury to the arteries of the liver. In these cases, changes or additions to the procedure or a separate operation may be required. In extreme cases, the liver or the spleen may have to be removed.

The gas injected into the abdominal cavity during the procedure can enter the chest cavity and push aside the lungs (**pneumothorax**), leading to shortness of breath, if the diaphragm is

injured. The air will then have to be removed through puncture or insertion of a drain.

If the gas enters a blood vessel, it may lead to dangerous **gas embolism** as a result.

During the removal of the gall bladder, **gallstones** can enter the **abdominal cavity** and cause pain or inflammation or even an abscess in unfavourable cases.

Gall stones remaining inside the bile duct can cause colics if the duct is blocked or even dangerous **inflammation of the pancreas** (pancreatitis). The removal of the stones via cholangiography will then be required.

In the long-term, unnatural connections (**fistulas**) between the bile ducts and other organs or the body surface may form. Draining the bile through a drainage catheter inserted via the nose or the abdominal wall, or separate surgical intervention, will then be required.

The **closure** of vessels and bile ducts may sometimes become **leaky**, which may result in inflammation of the abdominal lining or internal bleeding.

Adhesions inside the abdominal cavity may lead to symptoms even years after the procedure, sometimes even resulting in obstruction of the bowels; they will then have to be removed surgically.

Incisional hernias, which are most likely to occur as a result of open surgery, may have to be closed surgically.

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.

Gender: M / F, age: _____ years, weight: _____ kg, height: _____ cm
 Geschlecht: m / w, Alter: _____ Jahre, Gewicht: _____ kg, Größe: _____ cm

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, Heparin, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

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, Heparin, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

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 surgery on the abdomen? yes no

Wurden Sie schon einmal im Bauchbereich operiert?

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

If so, what complications? _____
 Wenn ja, welche?

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

Do you drink alcohol regularly? yes no

Trinken Sie regelmäßig Alkohol?

If so, what and how much: _____
 Wenn ja, was und wie viel:

Do you have or have you ever had any of the following diseases or symptoms thereof:

Liegen oder lagen nachstehende Erkrankungen oder Anzeichen dieser 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).

Blutkrankung/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 Blutkrankungen/Blutgerinnungsstörungen?

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

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:

Gastrointestinal diseases? yes no

Duodenal ulcer, stomach ulcer, Chronic inflammatory diseases of the bowel (Crohn's disease, ulcerative colitis).

Magen-Darm-Erkrankungen? Zwölffingerdarmgeschwür, Magengeschwür, entzündliche Darmerkrankung.

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.

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

Any other: _____
Sonstiges:

Diseases of the respiratory tract (breathing passages) or lungs? yes no

Asthma, chronic bronchitis, emphysema, sleep apnoea (intense snoring with breathing interruptions), vocal cord/diaphragm paralysis.

Erkrankung der Atemwege/Lungen? Asthma, Lungenentzündung, Lungenemphysem, Schlafapnoe (starkes Schnarchen mit Atemaussetzern), Stimmband-Zwerchfelllähmung.

Any other: _____
Sonstiges:

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
Sonstiges:

Thyroid diseases? yes no

Underactive thyroid, overactive thyroid, nodes.
Schilddrüsenerkrankungen? Unterfunktion, Überfunktion, Knoten.

Any other: _____
Sonstiges:

Kidney diseases? yes no

kidney insufficiency, kidney inflammation, Kidney operations, Plasmocytoma, Kidney or ureter stones, Blood in the urine.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung, Nieren-OP, Plasmocytom, Nieren-oder Harnleitersteine, Blut im Urin.

Any other: _____
Sonstiges:

Liver diseases? yes no

Liver inflammation.

Lebererkrankungen? Leberentzündung.

Any other: _____
Sonstiges:

Communicable (contagious) diseases? yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____
Sonstiges:

Do you have a malignant tumour (cancer)? yes no

Leiden Sie an einer Tumorerkrankung (Krebs)?

Are you receiving or have you received chemotherapy? yes no

Erhalten oder erhielten Sie eine Chemotherapie?

Any other acute or chronic diseases / illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____

Bitte kurz beschreiben:



Medical documentation for the informative interview

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:

Planned procedure:

- laparoscopic removal of the gall bladder
 conventional removal of the gall bladder

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is **capable of making a decision** on the recommended procedure on his/her own and giving his/her consent for the procedure.
 Der/Die Patient/in besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.
- The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. These persons are capable of making a decision in the best interest of the patient.
 Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.
- Custodian's card healthcare proxy advance healthcare directive has been submitted.
 Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.

Place, date, time [Ort, Datum, Uhrzeit]

Doctor's signature [Unterschrift der Ärztin/des Arztes]

Patient's refusal **Ablehnung**

The doctor _____ has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me.

Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab.

Place, date, time [Ort, Datum, Uhrzeit]

Refusal of patient / legal guardian / witness if applicable
 [Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]

DECLARATION OF CONSENT

Please tick the appropriate boxes and confirm your statement with your signature below:

- I hereby confirm that I have understood all sections of this form.** I have read the entire form (5 pages). During the pre-procedure interview with the doctor _____, I received detailed information regarding the course of the scheduled procedure, the risks, complications and side effects associated with it as they apply to my particular case as well as the advantages and disadvantages of any alternative methods. **Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt wurde ich über den Ablauf der geplanten Maßnahme, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.
- I deliberately refrain from obtaining a more detailed explanation.** However, I hereby confirm that the doctor _____ instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks. **Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.

I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen, sowie auf erforderliche Änderungen oder Erweiterungen des Maßnahme.

I confirm that I am capable of following the instructions given to me by my doctor.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

- I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of the patient */ legal guardian(s) [Unterschrift Patientin / Patient / Betreuer]

Copy/Kopie:

- received/erhalten
 waived/verzichtet

Signature Copy received/waived
 Kopiererhalt/-verzichtet