

Documento SIRM

# Informed consent

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**SOCIETÀ ITALIANA di RADIOLOGIA MEDICA**  
**ITALIAN SOCIETY OF MEDICAL RADIOLOGY**

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# **Informed Consent**

“Patient information and consent forms”

by

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## *PRESENTATION*

*Dear SIRM Member,*

*We are all aware that no radiologic or MR diagnostic investigation can be performed without the subject's valid consent and that the subject must be given adequate information and sufficient data, including possible associated risks, to be able to make an informed decision about the examination.*

*The existence of many imaging facilities in Italy (even within the single local healthcare agency or ASL) has led to the development of many different informed consent forms which are at times apparently very different from one another.*

*In this context, the President and Executive Committee of SIRM wish to propose a series of uniform informed consent templates to meet the need expressed by many SIRM members from different centers across Italy to "speak the same language" and optimize patient management.*

*So, by collecting the information from various centers and after consulting the relevant SIRM Study Sections, we have produced these consent forms that each member can either adopt in their entirety or integrate with those already in use.*

*In this brochure you will find a series of informed consent templates regarding various branches of radiology. These templates can be used as a reference both by those who do not yet feel they have "satisfactory" consent forms and those who merely want to compare them with their own and do not intend to replace the forms that have been approved at a regional level or are in any case shared by the different local imaging facilities.*

*In the hope that you find these templates useful, we wish you every success in your work.*

*EC Representative  
Dr Antonella Calvisi*

*EC Representative  
Dr Roberta Polverosi*

*SIRM President  
Prof. Antonio Rotondo*

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## CONSENT SHEET

### PATIENT-RELATED DATA

SURNAME \_\_\_\_\_ NAME \_\_\_\_\_

DATE OF BIRTH \_\_\_\_\_ PLACE OF BIRTH \_\_\_\_\_

HOSPITAL DIVISION \_\_\_\_\_ HOSPITAL \_\_\_\_\_

Therapeutic and/or diagnostic and/or rehabilitation intervention \_\_\_\_\_

1. The subject is in possession of his faculties and is of legal age
2. The subject is not in possession of his faculties or is not of legal age. We thus identified:
a) the parent or legal guardian for minors
b) the tutor for legally incapacitated subjects
c) the subject's conservator
3. The therapeutic and/or diagnostic and/or rehabilitation intervention can be performed on the grounds of "state of necessity"

### INFORMATION PROVIDED

Has all of the following information been provided?	Yes	No
· Diagnosis		
· Outcomes and expectations		
· Procedure for performing the therapeutic and/or diagnostic intervention		
· Type of anesthesia (if planned)		
· Possible risks of healthcare interventions		
· Possible diagnostic – therapeutic alternatives		
· Consequences of omitting the diagnostic and/or therapeutic and/or rehabilitation intervention		
· Was any other documentation used ?		
· If so, which :		
· Was the patient given a copy of the consent form ?		
· Have you checked that the patient, or the person receiving the information, has adequate understanding of the information given and is aware of both the risks and benefits of the therapeutic and/or diagnostic and/or rehabilitation intervention ?		
· If the patient did not correctly understand the information, was he/she given additional information to achieve the goal ?		

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Doctor's signature and stamp \_\_\_\_\_

**PROVISION OF CONSENT**

I FULLY UNDERSTAND WHAT HAS BEEN EXPLAINED TO ME BY DR \_\_\_\_\_

**AND HEREBY GIVE MY CONSENT**  
TO UNDERGO THE PROPOSED  
THERAPEUTIC AND/OR DIAGNOSTIC  
AND/OR REHABILITATION  
INTERVENTION IN THIS FACILITY

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Patient's signature \_\_\_\_\_

- If patient is a minor consent is provided by both parents:

**Signature of the parents or legal guardian:**

\_\_\_\_\_

- If patient is incapacitated consent is given by the possible tutor

**Tutor's signature:** \_\_\_\_\_

**REFUSAL OF CONSENT**

I FULLY UNDERSTAND WHAT HAS BEEN EXPLAINED TO ME BY DR \_\_\_\_\_

**BUT DO NOT CONSENT**  
TO UNDERGO THE PROPOSED THERAPEUTIC AND/OR  
DIAGNOSTIC AND/OR REHABILITATION  
INTERVENTION IN THIS FACILITY

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Patient's signature \_\_\_\_\_

- If patient is a minor consent is given by both parents

**Signature of the parents or legal guardian:**

\_\_\_\_\_

If patient is incapacitated consent is given by the possible tutor

**Tutor's signature:** \_\_\_\_\_

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Doctor's signature and stamp \_\_\_\_\_

**DEPARTMENT OF RADIOLOGY**

**PATIENT INFORMATION AND CONSENT TO UNDERGO AN  
EXAMINATION**

**PATIENT**

Surname \_\_\_\_\_ Name \_\_\_\_\_

Place of birth \_\_\_\_\_ Date of birth \_\_\_\_\_

Weight (kg) \_\_\_\_\_ sex M F

**CLINICAL QUESTION :** \_\_\_\_\_

**What to tell the radiologist and what to bring with you.**

It is very important to tell the radiologist of the symptoms that led to your referral and to show him or her any previous radiologic and ultrasound images. If this is a follow-up visit you should bring your previous examination. The radiologist must have access to the results of any other instrumental examinations or specialist consultations and be shown the treating physician's report or the discharge summary from previous hospital admissions, if available.

**INFORMED CONSENT**

I, the undersigned, Mr/Ms \_\_\_\_\_ have read the information about the radiologic procedure proposed to me and have received clear and exhaustive answers to all of my questions. I am aware that this examination, like many healthcare procedures, is not completely free of risks or adverse reactions, and those applying to my specific case have been adequately explained to me. I have been told that all adequate measures and precautions have been taken to prevent and/or face any possible complication.

I therefore declare that :

- I consent to undergo the examination without the administration of contrast material.
- I do not consent to undergo the examination.

**FOR WOMEN: STATE OF PREGNANCY**

- YES
- NO
- DON'T KNOW

**Date** \_\_\_\_\_

**Signature in full of the patient or provider of consent** \_\_\_\_\_

**PROCESSING OF SENSITIVE DATA**

We inform you that Legislative Decree no. 196 of 30/06/2003 provides for the protection of persons with regard to the processing of sensitive information.

The data collected are used for diagnostic purposes only, to comply with specific institutional duties connected with clinical activities, are stored in the radiologic archive and in the radiology information system, and are handled only by authorized persons subject to the obligation of professional secrecy.

We request that you express your consent to the processing of your data by signing in the space provided below, in the absence of which we will be unable to perform the examination.

Date \_\_\_\_\_ Signature \_\_\_\_\_

**SECTION TO BE COMPLETED BY THE RADIOLOGIST**

**PATIENT CONSENTED TO THE EXAMINATION**

- YES
- NO (specify reason) \_\_\_\_\_

**PROPOSED EXAMINATION HAS BEEN REPLACED WITH \_\_\_\_\_**

**Radiologist's signature**



**PATIENT INFORMATION AND CONSENT FOR AN EXAMINATION  
REQUIRING INJECTED CONTRAST MATERIAL**

**TO BE COMPLETED BY THE TREATING/REFERRING PHYSICIAN**

PATIENT

Surname \_\_\_\_\_ Name \_\_\_\_\_

Place of birth \_\_\_\_\_ Date of birth \_\_\_\_\_

Weight (kg) \_\_\_\_\_ sex M F

**CLINICAL QUESTION :** \_\_\_\_\_

**KNOWN CONDITIONS**

- Asthma
- Diabetes
- Pharmacologically treated allergic disorder
- Renal failure (creatininemia.....)
- Recent use of nephrotoxic drugs (if so, specify).....  
(cyclosporin, cisplatin, aminoglycosides, betablockers, interleukin 2,  
hydralazine...)

**Previous administration of a contrast agent:**

- YES
- NO

**Previous allergic reaction to a contrast agent:**

- YES \*
- NO

**Previous allergic reaction to medications or other substances:**

- YES (specify)\*
- NO

**Current therapy with biguanides:**

- YES : the patient **MUST DISCONTINUE THE DRUG** 48 hours before and after  
the examination.
- NO

**\* PATIENTS WITH A HISTORY OF ALLERGIC REACTION TO CONTRAST  
AGENTS OR MEDICATIONS REQUIRE PRIOR DESENSITIZATION.**

**EXAMPLE:**

**24 h prior to the examination:**

**PREDNISON 25 mg - 1 tab every 6 h (total 100 mg)**

**3 h prior to the examination:**

**RANITIDINE 150 mg - 1 tab**

**12 h after the examination:**

**PREDNISON 25 mg - 1 tab**

**NB: where oral therapy is not possible, points 1 and 3 can be replaced with 20 mg METHYLPREDNISOLONE i.v., with a total dose of 80 + 20 mg, respectively**

**The requested examination shall not be performed if the patient has not been pre-treated.**

Date \_\_\_\_\_

Stamp and signature in full of the treating/referring physician \_\_\_\_\_

**TO BE READ AND COMPLETED BY THE PATIENT**

**To undergo an imaging test requiring the use of contrast media you are required to fast for at least 6 hours before the test, with the exception of normally taken medications that can be taken with a few sips of water.**

ADVERSE EVENTS: after the injection of contrast material you will feel a transient sensation of diffuse warmth. During and after the administration of iodinated contrast material there may be unwanted effects related to allergic reactions, which may be immediate or delayed. Depending on their severity, reactions can be **mild** (nausea, vomiting, pain at injection site), **moderate** (dyspnea, hypotension, tachycardia) or exceptionally **life-threatening** (severe arrhythmias, severe bronchospasm, cardiorespiratory arrest, acute renal failure). **Delayed reactions** (from 1 h to 7 days after the beginning of the injection) more commonly consist of skin rash, flu-like syndrome, gastrointestinal disorders. In the event of delayed allergic reactions you should go to the Emergency Department.

During the bolus infusion of contrast agent there is a chance that, due to anatomic reasons of vein fragility, the blood vessel ruptures with leakage of the contrast medium: in this case the swelling is treated with topical creams and warm wet compresses, and the treatment is continued at home if necessary.

**FOR PATIENTS UNDERGOING UROGRAPHY**

**Before the examination**

In order to ensure success of the examination, you are required to cooperate by adequately cleansing the bowel. This is achieved by doing the following:

- **Eat a low-residue diet** the day before the examination.
- **Take a laxative** for 2 nights before the examination in order to empty the bowel completely.

### **WHAT TO TELL THE RADIOLOGIST AND WHAT TO BRING WITH YOU**

It is very important to tell the radiologist of the symptoms that led to your referral and to show him or her any previous radiologic and ultrasound images. If this is a follow-up visit you should bring your previous CT scan. The radiologist must have access to the results of any other instrumental examinations or specialist consultations and be shown the treating physician's report or the discharge summary from previous hospital admissions, if available.

### **INFORMED CONSENT**

I, the undersigned Mr/Ms \_\_\_\_\_ have read the information about the radiologic procedure proposed to me and have received clear and exhaustive answers to all of my questions. I am aware that this examination, like many healthcare procedures, is not completely free of risks or adverse reactions and those applying to my specific case have been adequately explained to me. I have been told that all the adequate measures and precautions have been taken to prevent and/or face any possible complication.

I therefore declare that :

- I consent to undergo the examination with the administration of contrast material.
- I consent to undergo the examination without the administration of contrast material.
- I do not consent to undergo the examination.

### **FOR WOMEN: STATE OF PREGNANCY**

- YES
- NO
- DON'T KNOW

**Date** \_\_\_\_\_

**Signature in full of the patient or provider of consent** \_\_\_\_\_

### **PROCESSING OF SENSITIVE DATA**

We inform you that Legislative Decree no. 196 of 30/06/2003 provides for the protection of persons with regard to the processing of sensitive information.

The data collected are used for diagnostic purposes only, to comply with specific institutional duties connected with clinical activities, are stored in the radiologic archive and in the radiology information system, and are handled only by authorized persons subject to the obligation of professional secrecy.

We request that you express your consent to the processing of your data by signing in the space provided below, in the absence of which we will be unable to perform the examination.

.

Date \_\_\_\_\_ Signature \_\_\_\_\_

**SECTION TO BE COMPLETED BY THE RADIOLOGIST**

**CONSULTATION WITH THE ANESTHESIST**

- YES
- NO

**CONSENT TO THE EXAMINATION**

- YES
- NO (specify reason) \_\_\_\_\_

**PROPOSED EXAMINATION HAS BEEN REPLACED WITH \_\_\_\_\_**

**Radiologist's signature**

**INFORMED CONSENT**

**DOUBLE-CONTRAST BARIUM ENEMA**

SURNAME ..... NAME \_\_\_\_\_

ADMITTED \_\_\_\_\_ DH \_\_\_\_\_ OUTPATIENT CLINIC \_\_\_\_\_

XR NUMBER \_\_\_\_\_ CLINICAL QUESTION \_\_\_\_\_

REQUESTED EXAMINATION .....

Dear Sir/Madam,

The DOUBLE CONTRAST BARIUM ENEMA requires, for the correct evaluation of your pathologic condition, the intravenous administration of a vial of BUSCOPAN to relax the intestinal muscles.

Absolute contraindications to the administration of Buscopan are:

- hypersensitivity towards the active ingredient itself (hyoscine-N-butylbromide), glaucoma, severe prostatic hypertrophy or urinary retention, pyloric stenosis, paralytic ileus, ulcerative colitis, reflux esophagitis.

Unwanted effects are:

1. Dry mouth;
2. Dilated pupils;
3. Visual accommodation disturbances (blurred vision);
4. Increased ocular pressure;
5. Constipation;
6. Difficulty urinating;
7. Drowsiness;
8. Rarely, anaphylactoid reactions and anaphylactic shock.

In consideration of the fact that this examination is indispensable in your situation, you are invited to complete and sign the informed consent below:

I, the undersigned declare that I have been informed in detail by Dr..... of the Radiology Department about the need to undergo, as a result of my health condition, administration of a vial of Buscopan and subsequent air insufflation.

I also declare that I have been exhaustively informed about the purposes, procedure and risks related to the intravenous administration of Buscopan.

DATE \_\_\_/\_\_\_/\_\_\_

Prescribing doctor's signature \_\_\_\_\_

RADIOLOGIST'S SIGNATURE

PATIENT'S SIGNATURE

\_\_\_\_\_

\_\_\_\_\_

**PATIENT INFORMATION**

**MAGNETIC RESONANCE IMAGING**

**Information about the examination**

Magnetic resonance (MR) imaging is a diagnostic **technique** that **does not utilize ionizing radiation** or radioactive substances. MR imaging uses static magnetic fields and electromagnetic radiofrequency (RF) waves, similar to those used by radio and television.

MR imaging without contrast material is a noninvasive diagnostic test and, on the basis of current knowledge, it does not produce important biological effects on patients for whom it is not contraindicated, and it is performed according to safety regulations and standards.

Although there is no evidence of sensitivity of the embryo to the static magnetic fields and electromagnetic RF waves used in diagnostic MR examinations, **it is prudent not to perform MR imaging** in women **during the first trimester of pregnancy**.

**Performance of the examination**

Before undergoing an MR examination patients have to complete a special “patient history questionnaire” and “informed consent form” so we can rule out any possible contraindication for the examination.

To undergo an MR examination the patient will have to:

- (1) remove any make-up and hair spray,
- (2) leave any metallic, ferromagnetic or magnetic object or media (mobile phones, coins, watches, keys, ear-rings, brooches, jewels, hair clips, magnetic cards, credit cards, etc) in the changing room or in a locker,
- (3) remove any dentures and hearing aids,
- (4) remove contact lenses or glasses,
- (5) undress and wear the disposable gown provided by the attending staff,
- (6) use the headphones or earplugs provided by the attending staff.

The average length of a MR examination is about 20-40 minutes.

While the MR images are being captured the patient will hear a regular knocking noise of varying intensity. This is the normal sound produced by the machine. To obtain the best image quality and not compromise the diagnostic result, the patient will have to **keep very still for the entire duration of the examination, while breathing regularly**.

The MR staff are always present in the control room and ready to intervene if necessary. The patient is in constant visual and vocal contact with the operators who monitor the situation throughout the procedure. If at any time the patient should experience sensations such as claustrophobia, flushing, itching, shortness of breath, palpitations or fainting he or she should immediately alert the operators by pressing the special buzzer.

Date.....

Patient’s name and surname .....

PATIENT’S SIGNATURE .....

**PATIENT HISTORY QUESTIONNAIRE  
FOR MR EXAMINATION**

The "patient history questionnaire" aims to make sure there are no contraindications to the MR examination. The questionnaire must be accurately completed prior to the examination by every patient or legal guardian (in the case of minors), and signed by the attending radiologist. Positive answers to one or more of these questions may constitute an absolute contraindication to the examination

- Have you had an MR scan before? YES NO
- Do you suffer from claustrophobia? YES NO
- Have you ever worked (or do you work) as a welder, turner, auto body worker? YES NO
- Have you ever been involved in road traffic or hunting accidents? YES NO
- Have you suffered explosion-related injuries? YES NO
- Are you pregnant or possibly pregnant? YES NO
- Have you ever had an allergic reaction after receiving contrast material? YES NO
- Have you ever undergone surgery involving the: YES NO
- Head..... Abdomen .....
- Neck..... Extremities .....
- Chest.....Eyes.....
- Other.....

- To your knowledge, do you have one or more medical devices or metal objects inside your body ? YESY NO
- Do you have any of the following in/on your body:
- Cardiac pacemaker or other types of cardiac catheters ? ES NO
- Metal shrapnel or fragments ? YES NO
- Aneurysm clips (blood vessels), aorta, brain ? YES NO
- Artificial heart valves ? YES NO
- Stents ? YES NO
- Implanted defibrillator ? YES NO
- Spinal distractor ? YES NO
- Implanted insulin or medication pump ? YESY NO
- Metal devices in the ears or hearing implants ? ESYE NO
- Neurostimulators, electrodes implanted in the brain or subdurally ? SYES NO
- Other types of stimulators ? YES NO
- Intrauterine device ? YES NO
- Spinal or ventricular shunt ? YES NO
- Dentures or removable dental devices ? NO
- Implanted metal devices (from previous fractures, joint repair surgery, etc), screws, pins, wire, etc...? YES YES NO
- Other implants ? NO
- Where ? .....

- Is there a possibility that you might have implants/devices or other metal objects inside your body that you are NOT AWARE of ? YES NO
- Do you have eye lens implants ? YES NO
- Do you have any body piercing ? YES NO

Where ?.....  
Do you have any tattoos ? YES NO  
Where ?.....  
Are you wearing medicated skin patches ? YES NO

*Please note that exposure to magnetic fields or radiofrequency waves can cause the **loss of contraceptive effectiveness** of intrauterine devices (IUD) : if you have an IUD, by signing the consent form you provide your consent to undergo the MR examination.*

**INFORMED CONSENT**

I/the undersigned \_\_\_\_\_ born in \_\_\_\_\_  
on \_\_\_\_\_, in full possession of my faculties, **declare** that I have been adequately informed about the indication, usefulness, procedure, risks and contraindications of exposure to the electromagnetic fields generated by the MR machine, and that I consent to undergo the MR examination.

In particular (for women) I understand that, even though there is no evidence of sensitivity of the embryo to electromagnetic fields, performance of an MR examination is not recommended during the first three months of pregnancy, except in cases of an absolute and non-deferrable necessity.

Patient's signature \_\_\_\_\_

Date \_\_\_\_\_

If the patient is a minor, the signature of a parent or the legal guardian is required.  
I, the undersigned \_\_\_\_\_

Parent/Legal guardian of \_\_\_\_\_

Date and Place of birth \_\_\_\_\_

declare that I have been informed about the MR imaging procedure and hereby give my consent to have the examination performed.

Signature of the parent or legal guardian \_\_\_\_\_  
Date \_\_\_\_\_

The attending MR radiologist, having taken note of the patient's answers  
AUTHORIZES THE EXAMINATION TO BE CONDUCTED

YES  
NO

Radiologist's signature \_\_\_\_\_  
Date \_\_\_\_\_



**INFORMED CONSENT FOR  
AN MR EXAMINATION  
WITH CONTRAST MATERIAL**

I, the undersigned \_\_\_\_\_ born on \_\_\_\_\_  
in \_\_\_\_\_ and in full possession of my faculties

declare

that I have been exhaustively informed about the clinical indication, usefulness, procedure, and possible adverse reactions and risk factors relating to the administration of contrast material. In particular, I understand that:

-  The intravenous administration of a contrast agent is an integral part of the MR examination and, in some types of study, it is indispensable for achieving a correct diagnosis.

*On this subject, it is important to know that the characteristics of these agents are such that they can be safely employed, "bearing, however, in mind the general risks of hypersensitivity, characteristic of any injectable formulation" (Circular of the Ministry of Health 900.VI/11.AG./642 of 17.9.97).* Patients requiring an MR examination with an intravenous gadolinium-based paramagnetic contrast agent must undergo a preliminary serum **CREATININE** test and hand in the result to the MR medical staff to allow them to evaluate kidney function and rule out possible renal insufficiency.

This is because patients with severe and **moderate renal failure** injected with i.v. gadolinium-based contrast material are at higher risk, compared to the general population, of developing a rare condition known as **nephrogenic systemic fibrosis (NSF)**.

NSF is a rare disease characterized by a debilitating and life-threatening thickening of the skin and connective tissues.

- All dialysis patients, for whom the dialysis unit will have granted approval for the MR study, should undergo dialysis as soon as possible after the administration of contrast material. Although it is not known whether dialysis can actually prevent NSF, the data indicate that it accelerates elimination of the contrast agent from the body.

**It is not advisable to use gadolinium-based contrast agents in high-risk patients unless the diagnostic information is crucial and cannot be obtained by any other means.**

- Administration of contrast material can sometimes produce mild side effects (warmth, flushing, nausea, vomiting, headache, skin rash, itching) which clear spontaneously or after mild intravenous treatment. In very rare cases and with an incidence which cannot be predicted or quantified but which is very low, it may cause severe allergic reactions including anaphylactic shock. It is therefore necessary **to inform the attending radiologist of any type of allergy before the examination** is started.

- A radiologist expert in MR imaging is always present during the MR study and an resuscitation specialist is always on call within the healthcare facility to ensure prompt intervention in the event of an emergency.

- The use of gadolinium in pregnant women requires a risk-benefit analysis (*Xagena 2003*)  
Source: *UCSF (University of California San Francisco)*, so the **MR radiologist must be informed of any pregnancy before the examination.**

**It is also recommended to inform the MR radiologist of breastfeeding** to arrange how and for how long to discontinue nursing after undergoing MR imaging.

- Any clarification about the MR study can be obtained from the staff of the MR unit.

I, the undersigned, in full possession of my faculties, have been informed about the risks connected to the possible use of contrast material for the MR examination and hereby give my consent to its use:

YES

NO

Date \_\_\_\_\_

Patient's signature \_\_\_\_\_

Attending radiologist's signature \_\_\_\_\_

If the patient is a minor, the signature of a parent or the legal guardian is required.

I, the undersigned \_\_\_\_\_

Parent/Legal guardian of \_\_\_\_\_

Date and Place of birth \_\_\_\_\_

Declare that I have been informed about the MR imaging procedure and hereby give my consent to have the examination performed.

Signature of the parent or legal guardian \_\_\_\_\_

Date \_\_\_\_\_

## INFORMED CONSENT

### MAMMOGRAPHY

Dear Madam

We wish to provide you with some information regarding **MAMMOGRAPHY**.

Mammography has a fundamental role in the early detection of breast cancer. It can, in fact, show changes in breast tissue that are small and/or which the patient is not aware of (non-symptomatic) and cannot feel. The first mammogram is indicated around the age of 35-40 years; mammography should then be repeated as advised by the radiologist. Because it is an imaging test that involves exposure to ionizing radiation, albeit at low dose, it should be avoided in the absence of a specific clinical indication

It should be kept in mind that the **RADIATION utilized in mammography can HARM THE FETUS** so, if there is a chance that you may be pregnant, you should tell the technologist before the examination. With some exceptions, radiation should be avoided in young women under the age of 30-35 years, since it has been suggested that it may have a carcinogenic effect on developing breasts.

If you have **BREAST IMPLANTS**, you are kindly requested to inform the technologist before the examination. The machine automatically selects the lowest possible dose for each type of breast, but with breast implants the dose selected is incorrect as the machine is unable to recognize the implants.

Also, please inform us if you have a pacemaker or Port-a-Cath.

**In some cases**, the examination, which involves a slow and progressive compression of the breast, can cause **discomfort, rarely pain**. If your breast feel very tender before the examination, please tell the technologist.

**Please note that mammography has some limitations**. Its accuracy is between 70% and 90%, which in practice means that it is unable to recognize a certain number (around 20%) of cancers, even if palpable, especially in dense breasts. Therefore please let us know if you have a palpable lump, skin retraction or nipple discharge. Should any of these appear shortly after mammography make sure you tell your doctor and get in touch with us.

Mammography can be difficult to interpret so, if your radiologist sees any findings deserving further investigation or particularly dense breasts (common in young women) on analyzing the mammogram, you will be recalled for additional radiographs or ultrasound. **This is routinely done to give patients a more definite answer and should not be a cause of anxiety.**

For the analysis of a mammogram to be more accurate, the radiologist should be able to compare it with previous imaging tests; each breast is different and has its own "normal appearance". A potentially questionable finding is not important if it has been there, unchanged, for years; on the other hand, the appearance of a small finding that was not there

before can help us detect a small cancer. We therefore invite you to **always bring with you any previous MAMMOGRAPHIC and ULTRASOUND STUDY.**

**Should we recommend that you undergo a short-term follow-up examination,** we can normally fix the date directly or else we will contact you to arrange a date. However, should you not hear from us, please call us on the following number (Tel.....).

The MAMMOGRAPH we use is a new-generation system equipped with a computer that allows us to establish the lowest and best radiation dose for each breast. The dose is normally recorded on each mammogram.

Regular tests are run to check the quality of the mammograms and the dose delivered.

The radiologists and technologists are specially trained and kept up to date in breast imaging.

**TO BE FILLED OUT:**

Surname (maiden name).....Name.....

Date of birth .....Street.....

No..... City.....Tel.....

**Having carefully read the above information and asked the radiologist to clarify any doubts:**

I CONSENT

I DO NOT CONSENT

to undergo: (check appropriate box)

MAMMOGRAPHY

BREAST ULTRASOUND

PATIENT'S SIGNATURE

Date.....

.....

## INFORMED CONSENT

### BREAST NEEDLE BIOPSY, NEEDLE ASPIRATION or LOCALIZATION

**Type of exam:** Core needle biopsy  
Fine needle aspiration biopsy  
Wire localization  
Radioactive dye localization

**Reason for the procedure:**

..... ..

**What do the procedures consist of:**

**Core needle biopsy** consists in using a needle to collect (4 to 10) tissue cores of a lesion identified on palpation, mammography, ultrasound and MR imaging. The biopsy takes place after injection of a local anesthetic.

The specimen collected is sent to the Pathology Laboratory for histologic analysis

**Fine needle aspiration biopsy** consists in using a thin needle (usually a normal injection needle) to collect (2, or 3 or 4) samples of cells or fluid from a lesion identified on palpation, mammography, ultrasound and MR imaging.

No anesthetic is given, as this would interfere with the biopsy procedure (no one uses anesthesia for an injection in the buttock, which is usually more painful than one in the breast).

The specimen collected is sent to the Pathology Laboratory for cytologic (cell) analysis; if the procedure is done to empty a cyst, the fluid is examined in specific cases only.

The result of histology (core needle biopsy) or cytology (needle aspiration biopsy) must be assessed in light of the diagnostic suspicion arising out of the clinical examination, mammography and ultrasound; for this reason, you will be given the result by the radiologist, who will explain what to do next.

If the histologic or cytologic analysis is negative (benign lesion) or inadequate, and review of the images suggests a benign lesion, you will be invited to undergo a follow-up examination with ultrasound, mammography or possibly MR imaging, after a short time interval. We can normally fix the date directly or else we will contact you to arrange a date. However, should you not hear from us, please call us on the following number (Tel.....).

**Preoperative localization** involves the insertion of a thin needle inside the lesion which the surgeon is going to excise. The needle is used to deliver a thin metal wire into the lesion (to be left in place and removed after surgery) or to inject a few drops of radioactive liquid, depending on the type of localization procedure agreed with the surgeon.

Predictable associated risks:

The risks are infection and bleeding. Infection is very rare, partly because specific rules are applied to work under sterile conditions. Bleeding is normally limited to bruising. However, we are at your disposal for any further clarifications.

A rare, though reported, event is pneumothorax, which is the accidental puncture of the lung pleura.

In patients with BREAST IMPLANTS there is a risk of perforating the implant.

Having understood the information given to me, I hereby freely and knowingly:

**Consent**  (or **Do not consent** ) to undergo the procedure described above, also in consideration of the temporary or permanent foreseeable consequences resulting from the proposed procedure

**Authorize**  (or **Do not authorize** ) use of the findings and images in anonymous form for educational and/or scientific purposes, in full compliance with the law.

I am aware that it is my right to ask for further explanations at any time.

I am also aware that I can revoke the decisions expressed at any time before the procedure is performed.

**Signature of patient** (or legal guardian) .....

Name and Surname of *legal guardian* .....

**Doctor's Stamp and Signature** .....

## INFORMED CONSENT

### VACUUM-ASSISTED BIOPSY PROCEDURE

#### DESCRIPTION OF PROCEDURE

Vacuum-assisted biopsy uses ultrasound/stereotaxis as guidance for placing a needle through which we can collect tissue samples from the nodule or area showing structural changes, samples which will be analyzed by histologic examination.

#### RISKS OF THE PROCEDURE

The procedure is done under local anesthesia.

Occasionally, during one of the needle passes, you may feel transient pain due to injury of a small nerve. This event is uncommon and unpredictable. The possibility of infection, bleeding, pneumothorax is rare.

#### POSSIBLE DISCOMFORT

**During the days immediately following the biopsy procedure you may have slight pain and redness of the skin at the biopsy site. At follow-up ultrasound one week after the procedure a small bruise may be seen, but the compression bandage applied over the dressing usually prevents any bruising.**

#### ALTERNATIVES TO THE TECHNIQUE

For the diagnosis of questionable lesions, an alternative to the VAB procedure is to follow up the finding over time by using mammography and/or ultrasound. However, there is a risk of delaying a diagnosis of malignancy. For the diagnosis of suspicious lesions, the only alternative is surgical excision.

#### RESULTS AND INDICATIONS

**Histologic examination of the biopsy cores allows for a definite diagnosis in a high percentage of cases. Therefore if the histology report indicates a benign lesion we will recommend clinical and imaging follow-up after three months. Conversely, if the result indicates a malignant lesion we will guide you in your path towards surgery.**

The doctor performing the biopsy procedure will assess the need to leave a small nonmagnetic (titanium-collagen) clip inside your breast to facilitate visualization of the lesion on future imaging tests and enable monitoring of changes over time.

#### CONSENT

I, the undersigned Ms. \_\_\_\_\_, declare that I have been adequately informed about the breast biopsy procedure carried out with the VAB system and about the possible associated risks and consequences. I confirm that I have fully understood the explanations given to me and hereby consent to undergo this procedure.

Date .....

Legible signature

## INFORMED CONSENT

### BREAST MRI

#### **What happens during the exam**

You will be asked to lie face down on a special patient support that will slide into the MRI system (a large cylinder open at both ends), with your breasts placed in special openings.

MRI relies on the use of radiofrequency waves (no x-rays are used) which have limited risks for the patient. Although not painful, you may find the exam distressing because of the noise of the machine.

During the exam, which may last between 20 and 40 minutes, you will have to keep very still.

Some patients experience **claustrophobia**. If this occurs, the MRI study can be interrupted.

If you think you might have this kind of problem, please notify the MRI staff before undergoing the study.

The images acquired have to be processed, and this takes up to several hours. For this reason we are unable to anticipate any information about the results of the scan.

Breast MRI always requires the **intravenous injection of a substance (paramagnetic contrast medium) which allows us to recognize otherwise invisible lesions and, if malignant, to establish their extension.**

#### **To prepare for the exam you have to:**

- remove contact lenses, hearing aids, dentures, removable dental work, sanitary belt;
- remove hairpins, hair clips, glasses, watches, credit cards or other magnetic cards, pocket knives, money clips, coins, keys, clothes with metal fasteners, buttons, zippers, staples (e.g., applied to clothes at the dry cleaner's), brooches, nail files, scissors, and other metal objects;
- remove facial make-up and any body piercings;
- remove all clothes, including underwear, with hooks or metal parts (bra, bodysuit, etc) and wear the disposable gown provided by the attending staff.
- For the exam to be reliable, it should be **performed between the 7th and 21st day of the menstrual cycle**, during the fertile period, or after discontinuing hormone replacement therapy, if used. If in doubt, please ask the radiologist in charge of the exam.
- To make sure we can evaluate the images, please take care to remain **absolutely STILL** once positioned on the patient table.

**A PACEMAKER IS AN ABSOLUTE CONTRAINDICATION TO THE EXAMINATION.**

**If you are PREGNANT or have CLIPS, IMPLANTS OR METAL IMPLANTS** you will have to contact the MR technologists or radiologist before the exam.



**It is important to remember that MRI suffers some limitations.** In some cases, in fact, it does not allow for an early diagnosis of malignancy, for example when this is represented by microscopic calcifications, which can only be seen on mammography. For this reason, **MRI cannot replace mammography in the early detection of cancer and should only be performed in predefined cases.**

This explains why we do not consider it correct to perform MRI on women who have not been previously and recently imaged with mammography and ultrasound.

For an accurate interpretation, breast MR images have to be assessed in relation to the relevant clinical history, and the previous mammograms and ultrasound images. In fact, breast MRI must only be used to solve diagnostic problems arising when assessing conventional imaging. **We therefore invite you to always bring with you all your breast documentation and at least the last MAMMOGRAMS AND ULTRASOUND IMAGES.**

MRI may be difficult to interpret. As a result, if on analyzing the images the radiologist sees findings that deserve further investigation, he might ask you to undergo “targeted” ultrasound. This is a normal breast ultrasound study with the only difference that is guided by the MR image and therefore more precise.

**Should we recommend that you undergo a short-term follow-up examination,** we can normally fix the date directly or else we will contact you to arrange a date. However, should you not hear from us, please call us on the following number (Tel.....).

**Prior to undergoing the MRI study you will have to complete the “Patient History Questionnaire” and the “Informed consent form for the administration of contrast material”**

Having understood the information given to me, I hereby freely and knowingly:

- **Consent** · (or **Do not consent**· ) to undergo the procedure described above, also in consideration of the temporary or permanent foreseeable consequences resulting from the proposed procedure.

**Signature of the patient** (or legal guardian) .....

Name and Surname *of legal guardian* .....

**Doctor’s stamp and signature** .....

## INFORMED CONSENT

### PERCUTANEOUS NEEDLE BIOPSY

On (date) \_\_\_\_\_ the staff of the Department of \_\_\_\_\_ of the Hospital \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

### CLINICAL ANAMNESTIC EVALUATION

Section to be completed by the attending physician of the referring ward, in order to classify the patient's level of risk (Circular of the Ministry of Health of 17/09/97) :

-Known risk of allergy	YES	NO (if yes, specify: _____)
-Severe liver failure	YES	NO
-Severe cardiovascular failure	YES	NO
-Severe kidney failure	YES	NO
-Other major conditions _____		

(Attending physician's signature) \_\_\_\_\_

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve the use of X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant**.
- The procedures described in the following sections involve the injection of a "**contrast agent**". This drug can rarely cause adverse reactions which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

### PATIENT INFORMATION AND STATEMENT OF CONSENT

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

#### PERCUTANEOUS NEEDLE BIOPSY

Percutaneous biopsy or needle biopsy is performed using thin needles with a diameter between 0.8 and 2 millimeters which enable the collection of samples of cells or tissue to be subjected to cytologic and/or histologic analysis in order to identify the nature of your disease. In the majority of cases percutaneous biopsy gives good results, and allows the most appropriate treatment strategy to be planned. Percutaneous biopsy is almost always performed with local anesthesia: exceptions are fine needle aspiration biopsies of superficial organs such as the thyroid or breast. However, if these organs are sampled for histologic analysis a local anesthetic is necessary.

**SUCCESS RATE AND RISKS** - Percutaneous biopsy carries a risk of rare complications, the most common being pain at the puncture site and small hematomas.

Major complications (including hemorrhage) are very rare. Death is exceptional. Other specific complications depend on the organ being sampled. For example:

- the most common complication of *pulmonary needle biopsy* (almost always done with the guidance of computed tomography) is pneumothorax (a collection of air in the pleural cavity resulting in partial collapse of the lung): collections with a thickness smaller than 3 cm need to be monitored over time (for at least 3-4 hours) by chest radiography, whereas larger collections can be drained (and resolved) by using special drainage catheters inserted directly by the radiologist.
- complications in *liver biopsy* (usually done under ultrasound guidance) can result from puncturing the liver parenchyma and blood vessels situated along the path that the needle has to follow to reach the lesion to be sampled. Generally, these complications are minor and transient (hematoma at the puncture site); in rare cases they may be more severe (bleeding with intrahepatic hematomas, hemobilia, hemoperitoneum, pneumothorax, hemothorax, cardiac arrhythmias, etc) and therefore require immediate or deferred treatment, even by means of surgery.

**ALTERNATIVES TO NEEDLE BIOPSY** – There are no (less invasive) alternatives to needle biopsy capable of guaranteeing the same results (diagnosis of the nature of the lesion), given that needle biopsy itself is an alternative to exploratory surgery.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided exhaustive answers to all of my questions and requests for clarification regarding:

.....  
.....:  
.....

**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

In light of the above, on (date) \_\_\_\_\_ I, the undersigned, declare that I

**CONSENT TO UNDERGO THE FOLLOWING  
DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE:**

TYPE OF EXAM/INTERVENTION	PATIENT'S SIGNATURE
PERCUTANEOUS NEEDLE BIOPSY	

Date \_\_\_\_\_ Doctor's signature: Dr./Prof. \_\_\_\_\_

**The radiologist is at your disposal for any further clarification.**

## PATIENT INFORMATION – INFORMED CONSENT

### DIAGNOSTIC ANGIOGRAPHY

On (date) \_\_\_\_\_ the staff of the Department of \_\_\_\_\_ of the Hospital \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

#### CLINICAL ANAMNESTIC EVALUATION

Section to be completed by the attending physician of the referring ward, in order to classify the patient's level of risk (Circular of the Ministry of Health of 17/09/97) :

- |                                |     |    |                          |
|--------------------------------|-----|----|--------------------------|
| -Known risk of allergy         | YES | NO | (if yes, specify: _____) |
| -Severe liver failure          | YES | NO |                          |
| -Severe cardiovascular failure | YES | NO |                          |
| -Severe kidney failure         | YES | NO |                          |
| -Other major conditions .....  |     |    |                          |
| .....                          |     |    |                          |

(Attending physician's signature) .....

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve the use of X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant**.
- The procedures described in the following sections involve the injection of a "**contrast agent**". This drug can rarely cause **adverse reactions** which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

#### DIAGNOSTIC ANGIOGRAPHY

This term refers to a diagnostic examination carried out through the introduction of special tubes (catheters) into an artery to be able to reach the vascular district of interest. Normally, the catheter is introduced into the femoral artery (in the groin) or, more rarely, into the radial artery (in the wrist), brachial artery (in the bend of the elbow) or into the axillary artery (armpit) or, in particular cases, other vascular accesses may be chosen. These catheters are then advanced up to the structures to be studied. The injection of contrast medium causes opacification of the vascular district, so that x-rays can be used to better distinguish normal anatomic structures (organs and vessels) from diseased structures.

**POTENTIAL RISKS OF THE DIAGNOSTIC EXAMINATION** - Apart from hematomas (circumscribed blood collections) which are often caused by the puncture of the artery, angiography carries a risk of some complications:

- **Rare:** pseudoaneurysms (dilation of an artery); arteriovenous fistulas (shunts connecting

arteries and veins); vagal reactions (nausea, drop in heart rate and blood pressure) due to reflexes triggered by the puncture.

- **Exceptional:** acute occlusion (closure) of the vessel (due to thrombosis or embolism); cardiac complications (heart failure, myocardial infarction and death); severe neurologic complications (generally due to embolism, especially in the case of investigation of the arteries supplying the brain).

**RECOVERY AFTER THE DIAGNOSTIC EXAMINATION** – After the examination the doctor may recommend to stay in bed for up to 12/24 hours. In any case, to avoid the development of hematomas or blood leakage, **it is very important that patients follow the doctor’s instructions meticulously.**

**BENEFITS OF DIAGNOSTIC PROCEDURES AND ALTERNATIVES** – Angiography provides a clear depiction of vascular anatomy and therefore accurately indicates the possible presence of disease. This information makes it possible to plan the most appropriate therapy for your case: surgical or interventional angioplasty. In some cases, as an alternative to this diagnostic procedure, spiral CT or MR imaging can be done: however, both of these tests require an injection of contrast medium to opacify the vascular structures to be studied.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ **(block capitals)**, who provided exhaustive answers to all of my questions and requests for clarification regarding:

.....  
.....:  
.....

**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I CONSENT TO UNDERGO THE FOLLOWING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE:**

Type of exam/intervention	Patient’s signature
DIAGNOSTIC ANGIOGRAPHY	.....

**Date**..... **Doctor’s signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**

## INFORMED CONSENT

### DIAGNOSTIC ANGIOGRAPHY – ANGIOPLASTY

On (date) \_\_\_\_\_ the staff of the Department of \_\_\_\_\_ of the Hospital \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

#### CLINICAL ANAMNESTIC EVALUATION

Section to be completed by the attending physician of the referring ward, in order to classify the patient's level of risk (Circular of the Ministry of Health of 17/09/97) :

- |                                |     |    |                          |
|--------------------------------|-----|----|--------------------------|
| -Known risk of allergy         | YES | NO | (if yes, specify: _____) |
| -Severe liver failure          | YES | NO |                          |
| -Severe cardiovascular failure | YES | NO |                          |
| -Severe kidney failure         | YES | NO |                          |
| -Other major conditions .....  |     |    |                          |

(Attending physician's signature) .....

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve the use of X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant**.
- The procedures described in the following sections involve the injection of a "**contrast agent**". This drug can rarely cause adverse reactions which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

#### DIAGNOSTIC ANGIOGRAPHY

This term refers to a diagnostic examination carried out through the introduction of special tubes (catheters) into an artery to be able to reach the vascular district of interest. Normally, the catheter is introduced into the femoral artery (in the groin) or, more rarely, into the radial artery (in the wrist), brachial artery (in the bend of the elbow) or into the axillary artery (armpit) or, in particular cases, other vascular accesses may be chosen. These catheters are then advanced up to the structures to be studied. The injection of contrast medium causes opacification of the vascular districts, so that x-rays can be used better to distinguish normal anatomic structures (organs and vessels) from diseased structures.

**POTENTIAL RISKS OF THE DIAGNOSTIC EXAMINATION** - Apart from hematomas (circumscribed blood collections) which are often related to the puncture of the artery, angiography carries a risk of some complications:

- **Rare:** pseudoaneurysms (dilation of an artery); arteriovenous fistulas (shunts connecting

arteries and veins); vagal reactions (nausea, drop in heart rate and blood pressure) due to reflexes triggered by the puncture.

- **Exceptional:** acute occlusion (closure) of the vessel (due to thrombosis or embolism); cardiac complications (heart failure, myocardial infarction and death); severe neurologic complications (generally due to embolism, especially in the case of investigation of the arteries supplying the brain).

**RECOVERY AFTER THE DIAGNOSTIC EXAMINATION** – After the examination the doctor may recommend to stay in bed for up to 12/24 hours. In any case, to avoid the development of hematomas or blood leakage, **it is very important that patients follow the doctor's instructions meticulously.**

**BENEFITS OF DIAGNOSTIC PROCEDURES AND ALTERNATIVES** – Angiography provides a clear depiction of vascular anatomy and therefore accurately indicates the possible presence of disease. This information makes it possible to plan the most appropriate therapy for your case: surgical or interventional angioplasty. In some cases, as an alternative to this diagnostic procedure, spiral CT or MR imaging can be done: however, both of these tests require an injection of contrast medium to opacify the vascular structures to be studied. The angioplasty procedure starts with the performance of angiography (described above).

This type of procedure is commonly carried out with local anesthesia and consists in dilating the strictures (stenoses) present in vessel segments - or recanalizing (re-opening) completely obstructed vessel segments through the use of balloon catheters. By gradually and repeatedly inflating the balloon within the narrowed segment, we are able to dilate the vessel and restore its normal caliber.

Where the narrowing is due to atherosclerosis (presence of a “plaque”) inflation of the balloon flattens the plaque against the vessel wall, thereby reducing the narrowing.

While the balloon is inflated, the stretching of the artery may cause pain. Throughout the procedure the patient is constantly monitored by the doctor, **who should immediately be told of any discomfort felt during the procedure.**

On the basis of clinical and/or anatomic criteria, during angioplasty one or more metallic endoprotheses (stents) may be placed in order to preserve the dilatation achieved with angioplasty. A **stent** is a small, metal mesh tube (rarely covered in fabric) with thin walls which is mounted onto a balloon. Inflating the balloon expands the stent and locks it in place in the artery.

After some time, the treated artery may narrow again (restenosis) or new strictures may develop in other vessels: in these cases, if the clinical and anatomic conditions permit, another angioplasty procedure can be attempted.

**SUCCESS RATE AND RISKS** - Apart from what was stated above for diagnostic angiography, the risks of angioplasty are limited: **rarely**, a thrombosis may develop in the artery being dilated and/or an embolism in the segment below the procedure site, due to the plaque fragments or a thrombus becoming dislodged; **very rarely**, the artery may rupture at the site of the dilatation. Some of these complications may call for emergency surgery to correct the problem.

In the case of recanalization (re-opening) of complete vessel occlusions the success rate decreases and risk of complications increases, proportionately to the length of the occlusion.

The success rate and the risks of the procedure are closely related both to the type of lesion and to the patient's cardiovascular condition, and therefore cannot be precisely predicted until the procedure has started.

**ALTERNATIVES TO REVASCULARIZATION WITH ANGIOPLASTY** - The alternative to angioplasty is conventional surgery.

**RECOVERY** – After an angioplasty procedure it is very important that patients follow the doctor's advice on postprocedure behaviors and medical treatment meticulously.

Now, therefore, I the undersigned....., hereby declare that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided exhaustive answers to all of my questions and requests for clarification regarding:

.....  
.....

**and explained the consequences of a possible decision NOT to undergo this test/procedure:**

- **in the case of angiography:** my diagnostic work-up would be incomplete so that it would be impossible to prescribe the appropriate therapy;
- **in the case of angioplasty:** I would have to continue with pharmacological therapy or undergo a surgical operation.

**I therefore declare that I am able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I CONSENT TO UNDERGO THE FOLLOWING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE:**

(tick)	Type of exam/intervention	Patient's signature
	DIAGNOSTIC ANGIOGRAPHY	.....
	ANGIOGRAPHY+ANGIOPLASTY	.....

**Date**..... **Doctor's signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**



PATIENT INFORMATION – INFORMED CONSENT

VARICOCELE SCLEROEMBOLIZATION

On (date) \_\_\_\_\_ the staff of the Department of \_\_\_\_\_ of the Hospital \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

CLINICAL ANAMNESTIC EVALUATION

Section to be completed by the attending physician of the referring ward, in order to classify the patient’s level of risk (Circular of the Ministry of Health of 17/09/97) :

- Known risk of allergy YES NO (if yes, specify: \_\_\_\_\_)
- Severe liver failure YES NO
- Severe cardiovascular failure YES NO
- Severe kidney failure YES NO
- Other major conditions .....
- .....
- (Attending physician’s signature) .....

Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:

- The procedures described in the following sections involve the injection of a “**contrast agent**”. This drug can rarely cause adverse reactions which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

The term phlebography refers to a diagnostic examination performed by inserting special tubes (catheters) in a vein in order to reach the diseased vascular region. Normally, the catheter is introduced into the femoral vein (at the groin) or, more rarely, into the jugular vein. These catheters are then advanced up to the structures to be studied. The injection of contrast medium causes opacification of the vascular regions, so that x-rays can be used to better distinguish normal anatomic structures (organs and vessels) from diseased structures.

**POTENTIAL RISKS OF THE DIAGNOSTIC EXAMINATION** - Apart from hematomas (circumscribed blood collections) which are often related to puncture of the vein, phlebography carries a risk of some complications:

- arteriovenous fistulas (shunts connecting arteries and veins); vagal reactions (nausea, drop in heart rate and blood pressure) due to reflexes triggered by the puncture of the vein, rupture of the vein, pulmonary embolism, testicular injury.

**RECOVERY AFTER THE DIAGNOSTIC EXAMINATION** - After the examination the doctor may recommend to stay in bed for up to 6/8 hours. In any case, to prevent hematomas or blood leakages **it is crucial that patients follow the doctor’s instructions meticulously.**

Patients are usually discharged on the same day and may resume light activity the following day and normal activity within a few days, depending on the individual situation.

**BENEFITS OF DIAGNOSTIC PROCEDURES AND ALTERNATIVES** – Phlebography provides a clear depiction of vascular anatomy and therefore reliably visualizes the possible presence of disease. This information makes it possible to accurately plan the most appropriate therapy.

**SUCCESS RATE AND RISKS** – Scientific studies have demonstrated a clear improvement in the function and number of sperm as well as in pain, without statistically significant differences between scleroembolization and surgery. The main differences are the length of stays in hospital and the rate of recurrences (5-10%), both of which are lower with interventional radiology.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** ..... **(block capitals)**, who provided exhaustive answers to all of my questions and requests for clarification regarding:

.....  
.....

**I therefore declare that I am able to make a reasoned decision.**

**In light of the above, on (date) ..... I, the undersigned declare that I**

**CONSENT TO UNDERGO THE FOLLOWING  
DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE**

(tick)	Type of examination/intervention	Patient's signature
	<b>SPERMATIC PHLEBOGRAPHY + VARICOCELE SCLEROEMBOLIZATION</b>	.....

**Date**.....

**Doctor's signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**

## INFORMED CONSENT

### EMBOLIZATION – CHEMOEMBOLIZATION - TIPS

On (date) \_\_\_\_\_ the staff of the Department of \_\_\_\_\_ of the Hospital \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

#### CLINICAL ANAMNESTIC EVALUATION

Section to be completed by the attending physician of the referring ward, in order to classify the patient's level of risk (Circular of the Ministry of Health of 17/09/97) :

- |                                |     |                             |
|--------------------------------|-----|-----------------------------|
| -Known risk of allergy         | YES | NO (if yes, specify: _____) |
| -Severe liver failure          | YES | NO                          |
| -Severe cardiovascular failure | YES | NO                          |
| -Severe kidney failure         | YES | NO                          |
| -Other major conditions .....  |     |                             |

(Attending physician's signature) .....

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve the use of X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant**.
- The procedures described in the following sections involve the injection of a "**contrast agent**". This drug can rarely cause adverse reactions which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

Angiography refers to a diagnostic examination carried out through the introduction of special tubes (catheters) into an artery to be able to reach the vascular district of interest. Normally, the catheter is introduced into the femoral artery (in the groin) or, more rarely, into the radial artery (in the wrist), brachial artery (in the bend of the elbow) or into the axillary artery (armpit) or, in particular cases, other vascular accesses may be chosen. These catheters are then advanced up to the structures to be studied. The injection of contrast medium causes opacification of the vascular districts, so that x-rays can be used to better distinguish normal anatomic structures (organs and vessels) from diseased structures.

**POTENTIAL RISKS OF THE DIAGNOSTIC EXAMINATION** - Apart from hematomas (circumscribed blood collections) which are often related to the puncture of the artery, angiography carries a risk of some complications:

- **Rare:** pseudoaneurysms (dilation of an artery); arteriovenous fistulas (shunts connecting arteries and veins); vagal reactions (nausea, drop in heart rate and blood pressure) due to reflexes triggered by the puncture.

- **Exceptional:** acute occlusion (closure) of the vessel (due to thrombosis or embolism); cardiac complications (heart failure, myocardial infarction and death); severe neurologic complications (generally due to embolism, especially in the case of investigation of the arteries supplying the brain).

**RECOVERY AFTER THE DIAGNOSTIC EXAMINATION** – After the examination the doctor may recommend to stay in bed for up to 12/24 hours. In any case, to avoid the development of hematomas or blood leakage, **it is very important that patients follow the doctor's instructions meticulously.**

**BENEFITS OF THE DIAGNOSTIC PROCEDURE AND ALTERNATIVES** – Angiography provides a clear depiction of vascular anatomy and therefore accurately indicates the possible presence of disease. This information makes it possible to plan the most appropriate therapy for your case: surgical or interventional angioplasty. In some cases, as an alternative to this diagnostic procedure, spiral CT or MR imaging can be performed: however, both of these examinations require an injection of contrast medium to opacify the vascular structures to be studied.

Embolization and chemoembolization are performed for treatment purposes at the same time as angiography.

In therapeutic vascular **embolization**, we introduce into the vessels particular materials and/or substances (particles of various substances, metal coils, sclerosing agents, ethyl alcohol, cyanoacrylic glues, etc) selected on the basis of the target lesion's characteristics, with the aim of achieving the temporary or permanent occlusion of the vessels.

In **chemoembolization** (most commonly used for the treatment of hepatic lesions), we inject into the artery chemotherapeutic drugs and iodinated oil (which by virtue of its texture fixes to the lesion prolonging its "contact" with the chemotherapeutic agent by weeks so as to obtain the desired therapeutic effect); normally, the procedure is completed by injecting fragments of Spongostan (sponge) or other material suitable for temporarily occluding the vessel.

**SUCCESS RATE AND RISKS** - The same considerations made on the subject of the complications of angiography, also apply to all cases of embolization and chemoembolization.

In particular:

- in **embolization** the substances injected into the vessels for therapeutic purposes may *accidentally* migrate to other vessels and cause ischemic damage in neighboring or distant vascular regions, skin ulcers or nerve injuries. These lesions are generally mild and reversible, but in rare cases they may lead to severe, at times permanent, functional and/or cosmetic damage, in some cases requiring corrective surgery.
- in **chemoembolization** there may be reactions to the drugs and substances injected, generally consisting of pain and fever with highly variable intensity and duration (few hours to weeks), altered liver function, altered blood cell count (anemia, thrombocytopenia, leukopenia), infections, cholecystitis. These complications are generally mild and reversible; in very rare cases life-threatening liver failure or pulmonary embolism may arise, despite the therapeutic measures taken. Hair loss is exceptional.

### **ALTERNATIVES TO EMBOLIZATION – CHEMOEMBOLIZATION**

The alternative to **embolization** is surgery, of which embolization is sometimes the first step (preoperative) or the last step (postoperative).

Chemoembolization is almost always reserved for cases not eligible for surgery or radiofrequency treatments: therefore the alternative to **chemoembolization**, at least in liver lesions, is nearly always medical treatment which has not, however, been proved to provide any valid clinical results.

Performance (or revision) of a transjugular intrahepatic porto-systemic shunt (**TIPS**) requires puncture of a vein (generally the right internal jugular vein in the neck) to insert a catheter which is advanced along the superior vena cava (the vein that brings the blood to the heart from the upper regions) in order to reach the right atrium of the heart and the inferior vena cava to reach a suprahepatic vein. At the same time, the liver parenchyma is crossed and a communication is created between a suprahepatic vein and the right or left branch of the portal vein (porto-systemic shunt) by placing an endoprosthesis or stent (after dilating the vessel); the stent serves to maintain the patency of the shunt.

**SUCCESS RATE AND RISKS** - in cases of performance or revision of a transjugular intraphepatic porto-systemic shunt (**TIPS**), there may be early complications such as porto-systemic encephalopathy (often resolved with medical therapy) or life-threatening complications such as hemoperitoneum (blood leakage into the abdomen). Late complications include infection, heart failure, liver and kidney failure, hemolytic anemia, thrombosis or restenosis of the shunt (which may be re-treated with a revision). The complication rate increases considerably in emergency procedures carried out due to acute bleeding.

**ALTERNATIVES TO TIPS** – The only alternative is conventional surgery (portocaval, mesocaval or splenorenal shunt), which was virtually abandoned after the advent of TIPS.

Central venous catheter placement refers to a procedure involving the identification of a central venous access (internal jugular vein, subclavian vein, femoral vein) and the insertion of a small tube known as a central venous catheter (CVC), which can be:

A – external

B – tunneled (partially inserted under the skin)

C – connected to a subcutaneous port (completely inserted under the skin)

**POTENTIAL RISKS OF THE PROCEDURE** - Like all medical-surgical practices, this procedure – even when performed with skill, diligence, prudence and under ultrasound guidance – presents a certain risk of complications and side effects. Among the specific complications related to the placement of a central venous catheter, some may be immediate (tenderness, hematoma, difficulty or inability to cannulate the venous access, arterial puncture, pneumothorax, hemothorax, development of arrhythmias, and other rarer complications). Other complications may arise during use of the central venous catheter (local infection, sepsis, thrombophlebitis, malfunction requiring replacement, other less common complications).

Because a central venous catheter is implanted with a surgical procedure, the formation of one or more scars is inevitable. After implantation of a “Port” device there may be raising of the skin or a bump in correspondence with the port reservoir, the extent of which varies with the amount of subcutaneous fat tissue.

**BENEFITS OF CVC PLACEMENT** – The procedure has many advantages, such as provision of a safe and lasting central venous access, immediately available for delivering medications, parenteral nutrition or blood products; the possibility of withdrawing blood without the need for additional venous punctures; and, as regards dedicated dialysis catheters, the possibility of performing hemodialysis in the absence of a fistula or during fistula malfunction.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided exhaustive answers to all of my questions and requests for clarification regarding:

.....  
.....

**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I**

**CONSENT**

**TO UNDERGO THE FOLLOWING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE:**

(tick)	Type of examination	Patient's signature
		.....

**Date**.....

**Doctor's signature: Dr./Prof.**.....

**The radiologist is at your disposal for any further clarification. Tel:**

**PATIENT INFORMATION- INFORMED CONSENT**

**CAVAL FILTER PLACEMENT**

**On (date) \_\_\_\_\_ the staff of the Department of \_\_\_\_\_ of the Hospital \_\_\_\_\_** provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

**CLINICAL ANAMNESTIC EVALUATION**

Section to be completed by the attending physician of the referring ward, in order to classify the patient's level of risk (Circular of the Ministry of Health of 17/09/97) :

- Known risk of allergy YES NO (if yes, specify: \_\_\_\_\_)
- Severe liver failure YES NO
- Severe cardiovascular failure YES NO
- Severe kidney failure YES NO

-Other major conditions .....

(Attending physician's signature) .....

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve the use of X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant**.
- The procedures described in the following sections involve the injection of a **“contrast agent”**. This drug can rarely cause adverse reactions which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

The procedure is carried out under local anesthesia and involves creating a central venous access (internal jugular vein, subclavian vein, femoral vein) and inserting a filter generally in the infrarenal inferior vena cava (hence the name caval filter) or in the superior vena cava (caval stent) to prevent severe pulmonary embolism.

The filter may be:

- A – temporary
- B – permanent, but possibly removable
- C – definitive

**POTENTIAL RISKS OF THE PROCEDURE** – The complications of venous catheterisation are rare and immediate (tenderness, hematoma, difficulty or inability to cannulate the venous access, arterial puncture, pneumothorax, hemothorax, development of arrhythmias, and other rare complications). Specific complications related to the caval filter itself are very rare. These include migration of the caval filter into the heart due to rupture of one of

its components; if this happens the filter can be retrieved with an endovascular technique, but if endovascular retrieval fails, open surgery is necessary. Another complication is the perforation of the vena cava wall by one of the filter's stabilizing legs; in these cases clinical and radiologic monitoring is recommended. Another possibility is thrombosis of the vena cava, which is also a very rare event, as are the other minor complications reported in the medical literature.

**BENEFITS OF CAVAL FILTER PLACEMENT** – A caval filter is shaped like an umbrella frame, the arms of which catch the embolic material that has migrated from the veins of the lower limbs or from the iliac veins (some thrombi are free to move in the vena cava – a free-floating thrombus - and have a greater risk of migration). By doing this, the filter prevents obstruction of the pulmonary arteries, which causes cardiocirculatory arrest in severe pulmonary embolisms.

Temporary caval filters are implanted to reduce the perioperative risk of embolism. Permanent, but possibly removable, caval filters can be left in place indefinitely. Definitive caval filters can only be removed by surgery.

**ALTERNATIVES TO CAVAL FILTER PLACEMENT** – There are no alternatives to caval filter placement, given that the filter itself is an alternative to surgery.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided exhaustive answers to all of my questions and requests for clarification regarding:

.....  
**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I**

**CONSENT  
 TO UNDERGO THE FOLLOWING  
 DIAGNOSTIC AND/OR THERAPEUTIC  
 PROCEDURE:**

Type of examination/intervention	Patient's signature
Placement of a caval filter	.....

**Date**..... **Doctor's signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**



**PATIENT INFORMATION – INFORMED CONSENT**

**INTERVENTIONAL RADIOLOGY  
BILIARY – URINARY - RADIOFREQUENCY**

**On (date)** \_\_\_\_\_ **the staff of the Department of** \_\_\_\_\_ **of the Hospital** \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

**CLINICAL ANAMNESTIC EVALUATION**

Section to be completed by the attending physician of the referring ward, in order to classify the patient’s level of risk (Circular of the Ministry of Health of 17/09/97) :

- Known risk of allergy YES NO (if yes, specify: \_\_\_\_\_)
- Severe liver failure YES NO
- Severe cardiovascular failure YES NO
- Severe kidney failure YES NO
- Other major conditions .....
- .....

(Attending physician’s signature) .....

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve the use of X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant.**
- The procedures described in the following sections involve the injection of a **“contrast agent”**. This drug can rarely cause adverse reactions which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

Interventional radiology, a technique performed with special instruments (needles, guidewires, catheters) under radiographic, ultrasound and/or CT guidance, makes it possible to perform procedures on the biliary or urinary tract and in many other organs (liver, pancreas etc.), which could once only be done with a surgical operation.

The examination will not only be useful to refine the diagnosis of your condition, but above all to treat it, and it does not preclude (in fact it often facilitates) subsequent surgery, if the result achieved is not optimal.

The examination is normally carried out with local anesthesia and mild sedation, with the exception of particularly complex procedures which may require deep sedation and/or general anesthesia.

The length of these procedures may range from a few minutes to more than an hour; a number of cases require more than one treatment to be delivered in separate sessions scheduled to take place days or weeks after the first procedure.

Biliary interventional radiology refers to procedures involving the insertion of special tubes (catheters) into the biliary tract when, some disease (gallstones, tumors, inflammation, compression) hinders the normal excretion of bile into the intestine (duodenum) with resulting

dilation of the biliary tract with jaundice of the skin and sclera and diffuse itching. The procedures aim both at demonstrating (or confirming, if the diagnosis has already been made on the basis of other diagnostic tests) the cause of the disease and at delivering the most appropriate treatment to restore the normal flow of bile.

The bile drainage catheters are normally inserted through the liver into peripheral bile duct that has been punctured with a thin needle; an injection of contrast material allows us to opacify the intra- and extrahepatic biliary tree and to better distinguish the normal and diseased anatomic structures.

Drainage catheters can be inserted into the bile duct, fixed to the skin and connected to a drainage bag outside the patient's body where the bile is collected (**external biliary drainage**); alternatively, they may be pushed downward to allow the bile to flow directly into the duodenum (**external-internal biliary drainage**).

- By using special catheters with a built-in inflatable balloon (balloon catheters), we can remove gallstones from the bile duct and push them into the duodenum.
- Balloon catheters can also be used to dilate strictures in the bile ducts or recanalize (re-open) completely occluded segments (percutaneous bilioplasty). While the balloon is inflated, distension of the bile duct can cause pain. The patient is constantly monitored throughout the procedure and **it is crucial that he tell the doctor immediately of any discomfort experienced in the course of the procedure.**
- To maintain the dilatation or recanalization of the bile duct obtained with bilioplasty, endoprotheses or **stents** can be inserted in the same manner as the biliary drainage catheter: these are small, meshed or perforated, metal or plastic tubes (the choice depends on the nature of the condition) which, by restoring the normal caliber of the bile duct, ensure that the bile can flow into the duodenum.

**SUCCESS RATE AND RISKS** – These procedures are not totally free of complications: there may be moderate bleeding, fever, and pain which normally require simple medical treatment; transient hemobilia (blood in the bile) should not be considered a complication. Not infrequently circumscribed biliary collections may develop which are readily treated with ultrasound-guided percutaneous drainage.

More severe complications such as major hemorrhage, hemoperitoneum, hemobilia may instead require transfusions and/or surgical or percutaneous repair. In fact, when hemobilia is caused by a severe injury to an artery of the liver, even with the formation of a pseudoaneurysm, it must be treated with percutaneous embolization to close the bleeding artery.

Other major complications are sepsis, biliary or abscess collections, cholangitis, pancreatitis, bile duct fissuring.

Very rarely death has been reported as a result of interventional procedures involving the biliary tree.

Urinary interventional radiology refers to procedures performed by inserting special tubes (catheters) into the urinary tract when, because of a disease (kidney stones, tumor, inflammation, compression), the normal excretion of urine is hindered, with the result that the urinary tract is more or less severely dilated.

Catheters for urine drainage (**nephrostomy catheter**) are normally inserted through the kidney by puncturing the renal pelvis with a thin needle; the injection of contrast medium allows the

upper collecting system (renal pelvis and ureter) to be opacified and thus makes it easier to distinguish between normal and diseased anatomic structures.

Nephrostomy catheters may be placed in the ureter, secured to the skin with a suture and connected to the urine bag, or they may be pushed further down to allow the urine to flow directly into the bladder.

- By using special catheters with an in-built balloon (balloon catheters), we can dilate ureteric strictures or recanalize (re-open) completely obstructed segments (***percutaneous ureteroplasty***). While the balloon is inflated, the distension of the ureter may cause pain. During the entire procedure the patient is constantly monitored by the doctor who should **immediately be told of any discomfort experienced in the course of procedure**.
- To maintain the dilatation or recanalization of the urinary tract obtained with ureteroplasty, endoprotheses or **stents** can be inserted in the same manner as the nephrostomy catheters: these are small perforated plastic tubes which, by restoring the normal caliber of the ureter, ensure the flow of urine into the bladder.

**SUCCESS RATES AND RISKS** – These procedures are not completely free of complications: pain, fever and gross hematuria (which tends to resolve spontaneously with 24-48 hours) are common events. In a small minority of cases the hematuria can require blood transfusion and/or surgical or percutaneous repair, the latter consisting of embolization of the bleeding vessel.

Exceptional complications are bleeding of an intercostal artery, pneumothorax, accidental puncture of the bile ducts or gallbladder, a renal colic. Very rarely, death has been reported as a result of interventional procedures involving the urinary tract.

**ALTERNATIVES TO INTERVENTIONAL RADIOLOGY** – There are no alternatives to biliary or urinary interventional radiology since the treatments described are themselves an alternative to endoscopic treatment or complementary to a surgical operation, which carries a higher risk of morbidity and mortality; medical therapy has no place in obstructive disease (with the exception of dialysis).

Radiofrequency (**RF**) consists in the destruction of diseased tissue by applying heat produced by a generator of electromagnetic waves (radiofrequency waves) connected to a needle inserted into the lesion being treated. Radiofrequency is currently used with satisfactory results in the treatment of liver lesions, especially primary lesions, but its use is extending to include other organs (kidney, lung) and, in selected cases, other sites. Normally, after the patient has been given local anesthesia, a small skin incision is made and, under ultrasound guidance, the needle is introduced through the liver and into the lesion, taking care not to cross its deep margin; the generator (which is connected both to the needle and to the patient by means of a metal plate placed on the patient's back) is then turned on, and by producing radiofrequency waves, it releases heat through the needle tip.

Heat at a temperature of 80-100 degrees centigrade is able to cause complete destruction (necrosis) of the diseased tissue which it comes into contact with.

The average duration of the entire procedure is approximately 15-45 minutes, but it may vary depending on individual needs: for example, lesions located very close to blood vessels, which subtract heat, or lesions larger than 3 cm in diameter may require several heat applications, each time with the needle in a slightly different position inside the lesion, in order to achieve

satisfactory results.

Radiofrequency treatments are performed with the patient under mild or deep sedation and with an resuscitation specialist present in the room. They are usually well tolerated by the patients as the local pain can be easily controlled with intravenous pain relief.

Radiofrequency is associated with some mild complications which occur more frequently, such as pain at the puncture site and small hematomas, whereas severe complications such as hemorrhage, hemoperitoneum, bilio-bronchial fistulas, bilomas (encapsulated bile collections), liver failure, abscess formation in the treated lesion are less common.

Very rare cases of death have been reported as a result of interventional procedures involving radiofrequency.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided exhaustive answers to all of my questions and requests for clarification regarding:

**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I**

**CONSENT  
TO UNDERGO THE FOLLOWING  
DIAGNOSTIC AND/OR THERAPEUTIC  
PROCEDURE:**

(tick)	Type of examination/intervention	Patient's signature
	BILIARY INTERVENTIONAL RADIOLOGY	.....
	URINARY INTERVENTIONAL RADIOLOGY	.....
	RADIOFREQUENCY	.....

**Date**.....

**Doctor's signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**

**PATIENT INFORMATION – INFORMED CONSENT**

**PERCUTANEOUS DRAINAGE**

**On (date)** \_\_\_\_\_ **the staff of the Department of** \_\_\_\_\_ **of the Hospital** \_\_\_\_\_ provided me with a copy of the present form in order to allow me to carefully read and evaluate the information contained herein.

**CLINICAL ANAMNESTIC EVALUATION**

Section to be completed by the attending physician of the referring ward, in order to classify the patient's level of risk (Circular of the Ministry of Health of 17/09/97) :

- |                                |     |                             |
|--------------------------------|-----|-----------------------------|
| -Known risk of allergy         | YES | NO (if yes, specify: _____) |
| -Severe liver failure          | YES | NO                          |
| -Severe cardiovascular failure | YES | NO                          |
| -Severe kidney failure         | YES | NO                          |
| -Other major conditions .....  |     |                             |
| .....                          |     |                             |

(Attending physician's signature) .....

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve exposure to X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant.**
- The procedures described in the following sections involve the injection of a "**contrast agent**". This drug can rarely cause **adverse reactions** which are classified as **mild** (nausea, vomiting, itchiness) or **moderate** (profuse vomiting, diffuse urticaria, facial edema, bronchospasm) and are generally resolved with simple treatment measures. Very rarely, the reactions may be **severe** (hypotensive shock, pulmonary edema, cardiorespiratory arrest).

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

Percutaneous drainage is performed with the patient under local anesthesia, using ultrasound or CT guidance to insert thin needles with a diameter less than 1 mm inside fluid collections to drain them and collect samples of the fluid to be analyzed by the laboratory to identify the nature of the collection and initiate a targeted antibiotic treatment.

Then, by using a coaxial system consisting of a guidewire and plastic tubes of increasing diameter from 2 to 5 mm, we introduce a tube with many holes (a drainage catheter) through which we can aspirate the fluid, wash out the area and, less commonly, deliver locoregional antibiotic therapy.

The drainage procedure gives good results and allows the most appropriate treatment strategy to be planned.

**SUCCESS RATE AND RISKS** – Percutaneous drainage is associated with rare complications, the most common being pain at the puncture site and small hematomas. Major complications (including hemorrhage) are very rare. Death is an exceptional occurrence. Specific complications will depend on the site of the collection:

- the most common complication of percutaneous drainage of a *pleural collection* is pneumothorax (collection of air in the pleural cavity leading to partial lung collapse): air collections smaller than 3 cm in size should be monitored for at least 3-4 hours by means of chest radiography; larger collections should be evacuated with special catheters which are placed directly by the radiologist or thoracic surgeon, and in these cases the observation period in hospital is prolonged to several days.
- drainage of *intraheptic collections* can cause bleeding due to injury to the vessels located along the path followed by the needle to reach the collection to be drained. These bleeds are generally mild and transitory. In rare cases, the bleedings are more severe with intraheptic hematomas, hemobilia, hemoperiteum, hemothorax, cardiac arrhythmias, etc, and therefore require adequate treatment, either immediate or delayed, even by means of surgical procedures.

**ALTERNATIVES TO PERCUTANEOUS DRAINAGE** – There are no (less invasive) alternatives to ultrasound- or CT-guided percutaneous drainage, capable of guaranteeing the same results (diagnosis of the nature of the collection), given that percutaneous drainage is in itself alternative to exploratory surgery.

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided exhaustive answers to all of my questions and requests for clarification regarding:

**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I**

**CONSENT  
TO UNDERGO THE FOLLOWING  
DIAGNOSTIC AND/OR THERAPEUTIC  
PROCEDURE:**

⋮

Type of examination/intervention	Patient's signature
PERCUTANEOUS DRAINAGE	.....

**Date**.....

**Doctor's signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**

## INFORMED CONSENT

### VERTEBROPLASTY/CEMENTOPLASTY

**Before describing the proposed diagnostic/interventional procedure, we request that you carefully read the following information:**

- The procedures described in the following sections involve exposure to X-rays, which is not recommended in **women of child-bearing age**, as it can damage the unborn baby. This means that, by signing the present form you are **declaring that you are not pregnant.**

In order to decide on the next steps in your clinical and therapeutic pathway, on the basis of the specific information produced by this exam, it is **necessary for us to provide you with the following information:**

#### DESCRIPTION OF PROCEDURE

The procedure consists of the injection, following local anesthesia, of orthopedic cement (polymethacrylate) into the vertebrae or bones of other districts by using a special needle placed under CT and/or fluoroscopy guidance.

#### AIMS OF THE PROCEDURE

This treatment has the sole aim of **treating pain**, which it achieves in **95% of cases**, and cannot replace any ongoing systemic treatments (chemotherapy, radiotherapy and medical therapy in osteoporosis).

#### POSSIBLE COMPLICATIONS RELATED TO THE PROCEDURE

(reported by the world medical literature as being very rare)

- Possibility of **cement leakage into the peridural space** during vertebroplasty (1 in 10,000 cases) to be treated with decompression surgery
- **Injury to the spinal cord or spinal hematoma** due to incorrect positioning of the needle with resulting **paraplegia** if the procedure is done on the mid-thoracic spinal segment (T6- T9) (1 in 10,000 cases)
- **Cement embolization** into a distal vein during vertebroplasty (symptomatic in 1 in 20,000 cases)
- **Cement leakage into the soft tissues along the needle path** during vertebroplasty and cementoplasty with resulting fibrosis (1 in 1000 cases) which is resolved by local steroid infiltration
- In rare cases, **bleeding**, which may be massive and require transfusion of blood or blood products

**Now, therefore, I the undersigned**....., hereby **declare** that I have read and understood the information contained in this consent form and that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives from **Dr./Prof.** \_\_\_\_\_ (**block capitals**), who provided

exhaustive answers to all of my questions and requests for clarification regarding:

.....

**and explained the consequences of a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

**In light of the above, on (date)..... I, the undersigned, declare that I**

**CONSENT  
TO UNDERGO THE FOLLOWING  
DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE:**

Type of examination/intervention	Patient's signature
VERTEBROPLASTY/CEMENTOPLASTY	.....

**Date**.....

**Doctor's signature: Dr./Prof.** .....

**The radiologist is at your disposal for any further clarification. Tel:**



**INFORMED CONSENT**

**EXPOSURE TO X-RAYS  
OF FEMALE PATIENTS OF CHILD-BEARING AGE**

I, the undersigned, Ms. .... born on .....  
Resident in ..... identity document no. ....

**DECLARE**

that I have been adequately informed about the potential risks, the technique adopted, the advantages resulting from the examination and the disadvantages related to the failure to undergo the examination by .....

that I exclude the possibility of pregnancy;

that, although I am unable to exclude the possibility of pregnancy, I consent to undergo the radiologic examination .....to be performed on (date) ..... at (time) .....

that, because I am unable to exclude the possibility of pregnancy, I refuse to undergo the radiologic examination .....

Should a pregnancy be demonstrated within seven weeks of the examination you are invited to contact your doctor.

Date.....

The radiologist/technologist .....

The patient.....

**BEFORE UNDERGOING A RADIOGRAPHIC  
EXAMINATION  
WOMEN OF CHILD-BEARING AGE  
MUST BE SURE**

**THEY ARE NOT PREGNANT**

**BECAUSE X-RAYS  
CAN HARM THE EMBRYO AND FETUS.**

**THE DAMAGE CAUSED BY X-RAYS INCLUDES:**

**MALFORMATIONS  
GROWTH DISORDERS  
MENTAL RETARDATION  
LEUKEMIAS OR OTHER CHILDHOOD CANCERS  
MISCARRIAGE**

**IF A WOMAN IS UNABLE TO EXCLUDE  
A PREGNANCY  
SHE SHOULD TELL THE PHYSICIAN  
REQUESTING OR PERFORMING THE  
RADIOGRAPHIC EXAMINATION.**

**PATIENT INFORMATION – INFORMED CONSENT  
WITH PERMISSION TO VIDEOTAPE**

I, the undersigned ....., following the meeting with the medical specialist Dr./Prof..... declare that I have been given comprehensible information regarding the examination.....

I also declare that I have been informed about the possible risks and complications associated with the examination to be performed:

.....  
.....

and of the possible side effects and secondary effects (unexpected adverse reactions) deriving from the use of the iodinated contrast agent called ..... required for the performance of the examination.

I also declare that I have received comprehensive information regarding the type of diagnostic and/or therapeutic procedure, the performance of the procedure, the resulting benefits for the purposes of establishing a precise diagnosis, the associated risks, and the pharmacological and surgical treatment alternatives, with exhaustive answers to all of my questions and requests for clarification concerning: .....

**and a clear explanation of the disadvantages deriving from a possible decision NOT to undergo this test/procedure and that I am therefore able to make a reasoned decision.**

I authorize and hereby give consent for my procedure to be photographed or videorecorded for educational and/or scientific purposes only, and fully safeguarding my rights to anonymity. I also authorize, in accordance with the privacy protection laws, the collection and processing of my personal data and their use and disclosure in anonymous form. (yes  no )

Failure to provide authorization for the above will not jeopardize the quality of the care that I am currently receiving and will receive in the future.

**In light of the above, on (date) ..... I, the undersigned, declare that I CONSENT TO UNDERGO THE FOLLOWING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURE:**

(tick)	Type of examination/intervention	Patient's signature
	.....	.....

**Date..... Doctor's signature: Dr./Prof. ....**

**The radiologist is at your disposal for any further clarification. Tel:**





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