

# Patient information

## Coronary artery disease and treatment options



Vascular Systems

# Patient information

## 1. Foreword

Dear Patient,

Within this booklet we would like to answer some of your questions on coronary artery disease (CAD), the diagnostic procedure and state of the art treatment options.

It should also help you to make the right decision on the appropriate treatment in agreement with your physician.

We have carefully selected all the important information. This booklet does not aim to replace the necessary discussion with your attending physician.

In case of further questions, please refer to your doctor or visit the following web site:  
[www.drugelutingballoon.com](http://www.drugelutingballoon.com)

At the end of this booklet you will find a glossary that provides definitions for all words printed blue.

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## 2. Coronary artery disease (CAD)

**Coronary artery disease (CAD;** also called coronary heart disease, CHD) is the most common form of heart disease in America and Europe and is a serious health problem worldwide. The incidence of CAD is lower in Asian countries, particularly Japan, where diets are low in saturated fat and cholesterol. CAD usually results from **atherosclerosis**, a condition that occurs when arteries become narrow and hardened due to cholesterol **plaque** build-up. **Myocardial infarction** (heart attack) can be a serious result of CAD, occurring when a blocked **coronary artery** causes death to a portion of the myocardium (heart muscle). Statistics show CAD to be the leading cause of death among both men and women in the United States and in Europe.

### 2.1. Who is at risk?

People with a history of high cholesterol, diabetes, smoking, high blood pressure, being overweight and a family history of CAD have an increased risk of developing **atherosclerosis** in the **coronary arteries**. Increasing age adds to the risk of CAD. In addition, menopausal status may play a role in women.

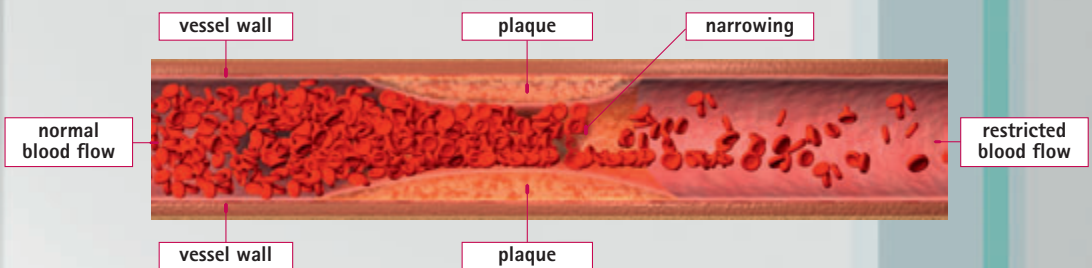
**Risk factors can be classified into controllable and uncontrollable risk factors (that you can influence):**

Controllable	Uncontrollable
▶ smoking	▶ age
▶ high cholesterol level	▶ gender
▶ hypertension	▶ family history
▶ lack of physical activity	▶ genetics
▶ obesity and excess of weight	
▶ diabetes mellitus	
▶ stress	

## 2.2. Oxygen deficiency (reduced blood flow)

The **coronary arteries** surround the heart and supply blood containing oxygen and nutrients to the heart muscle.

**Coronary artery disease** occurs when the **lumen** of the **coronary arteries** becomes narrowed with **plaque** deposits. **Plaque** deposits are a build-up of cholesterol and other fats, calcium and elements carried in the blood. The narrowing of the **coronary arteries** lead to a restricted blood flow and consequently an insufficient supply of oxygen and other nutrients to the heart.



Complete obstruction of a **coronary artery** can result in a heart attack (**myocardial infarction**) or a fatal rhythm disturbance (sudden cardiac arrest). Anyone who experiences **symptoms** of **angina pectoris** or **myocardial infarction** should promptly seek medical care.

## 3. Information on CAD

CAD is the n° 1 cause of death in the Western hemisphere and kills more than 2 million Europeans each year. However, treatment options for CAD have substantially improved in recent years, and many CAD patients are now able to return to a normal lifestyle shortly after treatment.

### 3.1. Typical symptoms (symptomatic CAD)

The most common symptoms are:

- ▶ Chest pain/angina pectoris
- ▶ Jaw pain
- ▶ Shoulder or arm pain involving left, right, or both sides during stressful physical or mental activity
- ▶ Shortness of breath
- ▶ Palpitation (a sensation of rapid or very strong heart beats in your chest), dizziness, light-headedness, or fainting
- ▶ Weakness on exertion or at rest
- ▶ Irregular heartbeat

No one person usually has all of these symptoms. Almost one third of the total patient population does not show any discomfort.

### 3.2. Silent ischemia (asymptomatic CAD)

In contrast to the typical symptoms silent ischemia is a condition in which no symptoms occur even though an electrocardiogram and/or other tests show evidence of ischemia. Arteries may be blocked 50 % or more without causing any symptoms.

### 3.3. Important information for diabetics

Diabetic patients have to be aware that they might perceive pain differently. They might not feel pain at all or as intense although they have a circulatory disorder of the heart. Therefore please be cautious and carefully pay attention to the signs of your body.



## 4. Diagnostics and tests

CAD is the end result of the accumulation of **plaques** within the walls of the arteries that supply oxygen and nutrients to the heart muscle. While the **symptoms** and signs of CAD are noted in the advanced state of disease, most individuals with CAD show no evidence of disease for decades. As it progresses before the first onset of symptoms, often a "sudden" heart attack, finally arises. After decades of progression, some of these **plaques** may rupture and (along with the activation of the blood clotting system) start limiting blood flow to the heart muscle. This is why medical professionals use screening tests to detect the presence and severity of coronary disease before it causes problems or send you to an emergency department with severe symptoms.

**The symptoms of coronary artery disease are what medical professionals call non-specific.**

- ▶ This means the **symptoms** could be caused by many different conditions, some not related to the heart at all.
- ▶ Upon hearing your **symptoms** your physician will begin a process of gathering information (anamnesis).
- ▶ The purpose of this is to rule out conditions and pinpoint the correct diagnosis.
- ▶ It includes asking questions about your **symptoms**, your medical and surgical history, your general health and specific medical problems and the **medication** you take.
- ▶ It will also include a physical examination, blood cholesterol tests, blood pressure measurements, **electrocardiogram (ECG)**, stresstests, chest **x-ray**, **coronary angiography**, **CT** or **MRI**.



## 5. The most common treatment options

**Coronary artery disease** may be managed through a combination of changes in lifestyle and physical activity, diet and medical treatment. The therapy your physician recommends will depend on the number, severity and location of the obstructions. Nitroglycerin is often given to relieve chest discomfort due to blockages, but does not treat the blockage itself.

Medical treatment of the blockage may include **medication**, **coronary angioplasty**, with or without stent implantation, or **coronary artery bypass graft surgery (CABGS)**.

To determine the best treatment for you and to fully understand the options you should discuss with your physician the benefits and risks that each treatment has.

### 5.1. Medication

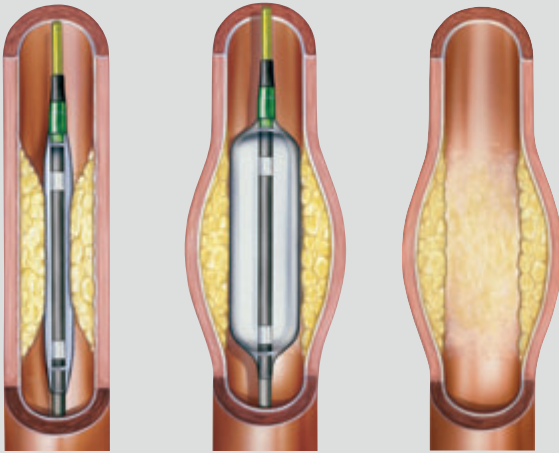
The conventional treatment option includes a number of medicines that can help relieve the **symptoms** of **CAD**. Most commonly used are acetylsalicylic acid (ASA), nitroglycerine, beta-blockers and calcium channel blockers.

### 5.2. Bypass surgery (CABGS)

Bypass surgery is open heart surgery that reroutes blood flow around a blocked vessel or vessels of the heart. The patient is under general anaesthesia and is not awake during surgery. Normal hospital stay is 5-6 days.

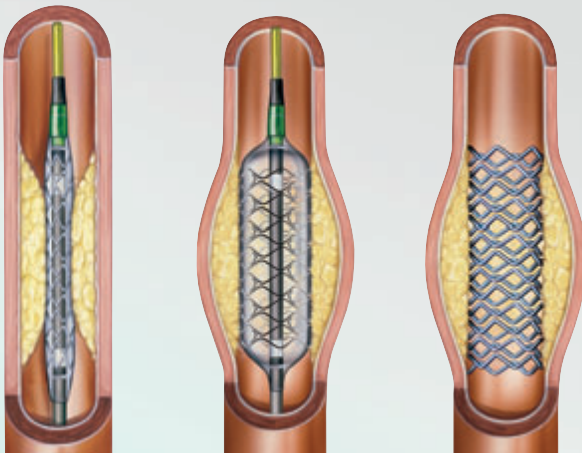


### 5.3. Coronary angioplasty (PTCA)



**Coronary angioplasty** – also called PTCA (percutaneous transluminal coronary angioplasty) – is a procedure in which a tiny balloon is expanded that presses the **plaque** blockage against the artery so that blood may flow more freely through the vessel. Normal hospital stay is overnight.

### 5.4. PTCA with stent



In addition to regular angioplasty a **stent** is inserted into an artery after angioplasty to help ensure that blood continues to flow freely through the vessel and to reduce the chance that **plaque** will block the artery again.

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A **stent** is a tiny, expandable metal coil that is inserted into the newly-opened area of the artery to help keep the artery from narrowing or closing again. Once the stent has been placed, tissue will begin to form over it a few days after the procedure. The stent will be completely covered by tissue within approximately one month. It is necessary to take medication, such as ASA and Clopidogrel, which decreases the "stickiness" of **platelets**, in order to prevent blood clots from forming inside the stent.

## 5.5. PTCA with Drug Eluting Stents

Drug-eluting stents (DES) are small wire meshes which are coated with a drug. This drug is slowly released into the wall of the blood vessel or artery and potentially reduces the chance that the artery becomes re-narrowed.

The implantation procedure of a DES is similar to the one of a bare metal stent (BMS = stent without drug coating).

## 5.6. PTCA with Drug Eluting Balloons

Please see section 7 of the patient information (pages 14 to 16).



## 6. PTCA – the non surgical procedure

When [angina symptoms](#) worsen despite [medication](#), you may need an invasive procedure in the cardiac catheterization lab to clear the blocked artery; a so called PTCA.

The previously mentioned [percutaneous](#) transluminal [coronary angioplasty](#) (PTCA) is a comparatively gentle intervention. The PTCA procedure is similar to the classic [coronary angiography](#).



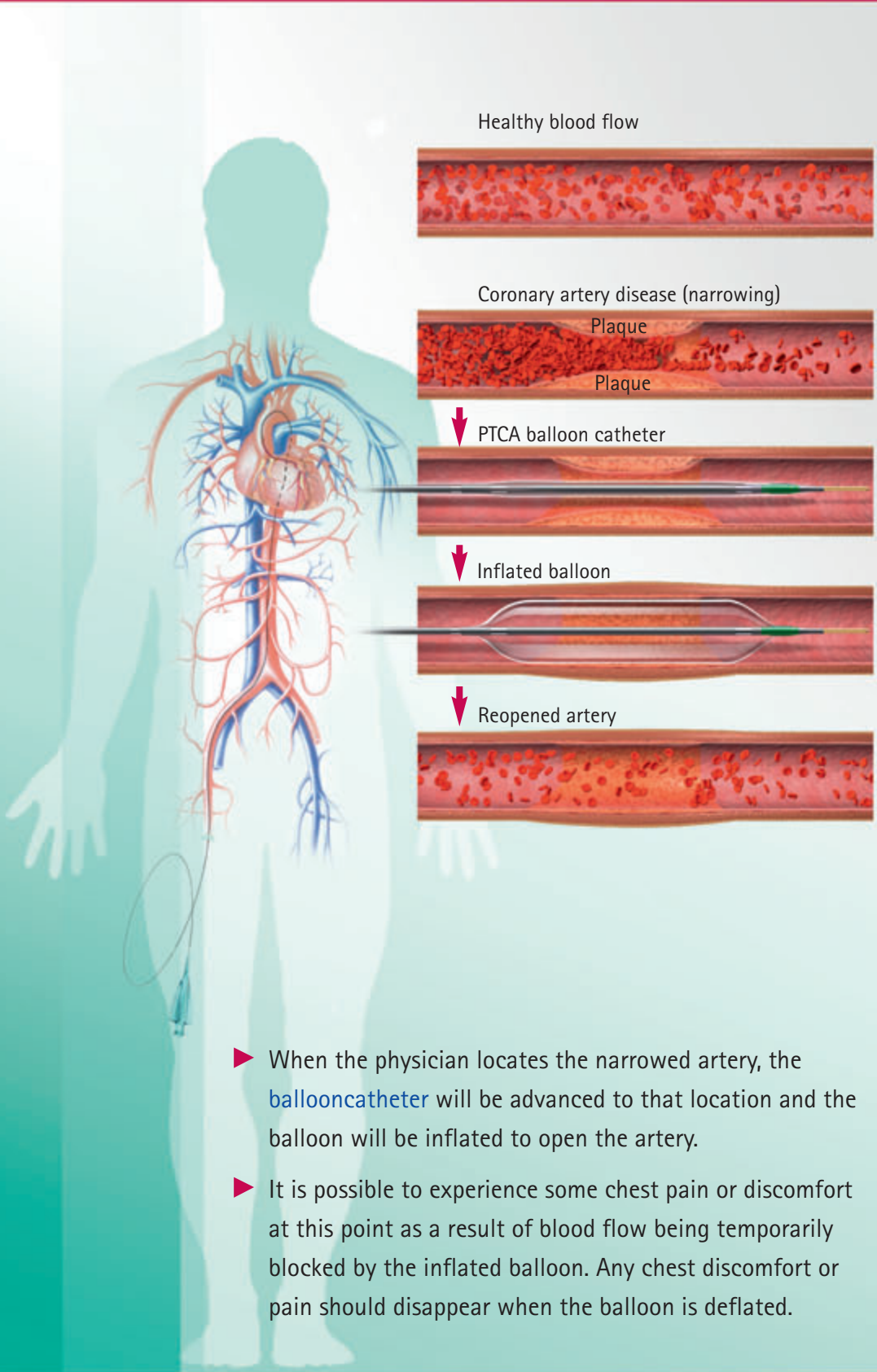
### How does it work?

PTCA may be performed as part of your stay in a hospital. Procedures may vary depending on your condition and your physician's practices.

**Generally, a PTCA (with stent) follows this process:**

- ▶ A local anaesthesia will be injected into your skin at the insertion site (groin or arm). You may feel some stinging at the site for a few seconds after the local anaesthetic is injected.
- ▶ Once the local anaesthesia has taken effect, an [introducer sheath](#) will be inserted into the blood vessel.
- ▶ The PTCA [catheter](#) will be inserted through the [introducer sheath](#) into the blood vessel. The physician will advance the PTCA [catheter](#) through the [introducer sheath](#) via the aorta into your heart. [Fluoroscopy](#) will be used to assist in advancing the [catheter](#) to the heart.
- ▶ The [catheter](#) will be advanced into the [coronary arteries](#). Once the [catheter](#) is in place, a [contrast agent](#) will be injected through it into your [coronary arteries](#) in order to see the narrowed area(s).

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- ▶ When the physician locates the narrowed artery, the [ballooncatheter](#) will be advanced to that location and the balloon will be inflated to open the artery.
- ▶ It is possible to experience some chest pain or discomfort at this point as a result of blood flow being temporarily blocked by the inflated balloon. Any chest discomfort or pain should disappear when the balloon is deflated.

- ▶ The physician may inflate and deflate the balloon several times. The decision can be made at this point to insert a **stent** (bare-metal or drug eluting stent) in order to maintain the artery open.
- ▶ In some cases, the physician may decide to implant a **stent**, without prior balloon dilatation (direct stenting). The **stent** is pre-mounted on a balloon catheter. The balloon inflation will open the artery and expand the **stent**.
- ▶ Once the physician has determined that the artery is sufficiently opened, the balloon **catheter** will be removed.
- ▶ The insertion site may be closed with a closure device that uses collagen to seal the opening in the artery by metal clips, by the use of sutures, or by applying manual pressure over the area to keep the blood vessel from bleeding. Your physician will determine which method is appropriate for your condition.
- ▶ Your vital signs (heart rate, blood pressure, breathing rate, and oxygenation level) will be monitored during the entire procedure.



## 7. PTCA with SeQuent® Please

### 7.1. Understanding the drug-eluting balloon (DEB) concept

Over the last 10 years, coronary stenting with bare-metal **stents** (BMS) and drug-eluting **stents** (DES) has become a primary treatment option for patients with **CAD**. There are certain limitations in the utilization of **stents** depending on the anatomical conditions of the vasculature (e.g. very small vessels, long diffuse lesions) or due to secondary disorders such as diabetics. One has also to differentiate between the treatment of a de novo lesion and an ISR (in-stent **restenosis**).

Compared to bare-metal **stents**, the DES have been shown to have significantly lower rates of in-stent **restenosis**. A known concern about DES is the risk of a so called late thrombosis i.e. a clot of blood cells rapidly blocking the vessel **lumen** several months after the stenting procedure. Accompanied by the typical **symptoms** described earlier, this event needs instantaneous treatment. Concomitant antiplatelet therapy is required at least for a couple of months in both stenting therapies (BMS and DES).

The only way to overcome these limitations and risks is the abdication of placing foreign material (i.e. a **stent**) into the vessel.



SeQuent® **re**LEASE



## The first clinically proven DEB

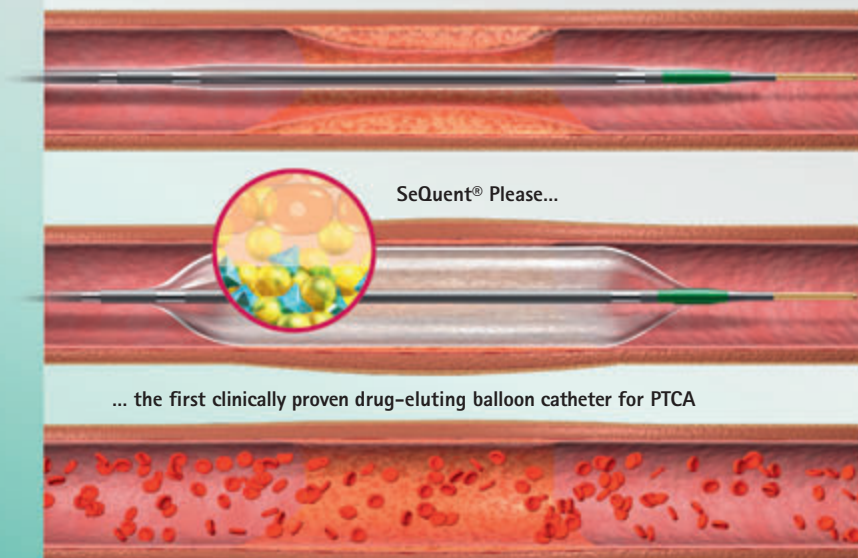
Enabled by new manufacturing techniques the classical **percutaneous** transluminal **coronary angioplasty** (PTCA) is taken up again to obtain a valuable solution to this problem.

SeQuent® Please is the first clinically proven PTCA balloon **catheter** with a surface coating on the balloon with an antiproliferative drug (Paclitaxel). SeQuent® Please opens blocked **coronary arteries** with a long-term effect without placing foreign material, i.e. it offers a greater extent of treatment options by decreasing the risk of side-effects.

### 7.2. Mode of action

The drug-eluting balloon **catheter** (SeQuent® Please) is inserted through the blood vessels across the blockage, and is inflated to open the blockage like regular PTCA balloon **catheters** (without drug coating).

SeQuent® Please is deployed across the blockage when it is in the right position. During the balloon inflation the antiproliferative drug is released from the balloon surface and delivered directly into the vascular wall.





## 7.3. Benefits for the patient

Drug-eluting balloons (DEB) are a viable alternative to drug-eluting stents in the treatment of [coronary artery disease](#).

### The advantages are:

- ▶ Long lasting patency (LTP)
- ▶ Low risk of restenosis
- ▶ No permanent implant
- ▶ Offers a new treatment option with superior results in complex lesions (ISR and small vessels)
- ▶ Unlimited treatment options in case of re-intervention
- ▶ Reduced duration of antiplatelet therapy

## 7.4. Contraindications of the DEB

The drug-eluting PTCA balloon catheter SeQuent® Please should not be used in patients who:

- ▶ Are contra-indicated to take blood-thinning drugs (antiplatelet and /or anticoagulation).
- ▶ Have a lesion that is highly calcified or otherwise could prevent access or expansion of the balloon catheter, i.e. are not suitable for a PTCA at all.

SeQuent® Please is safe and effective when used in accordance with its approved indications.

## 8. Post-treatment

### 8.1. After the procedure

After the balloon dilation with SeQuent® Please, you will be moved to a cardiology ward for a short time period where you can be monitored closely as you begin to recover. On average, your hospital stay may last one to three days before you are discharged.

### 8.2. Activity

#### We recommend:

- ▶ Follow your physician's recommendations.
- ▶ Return to normal activities gradually, pacing your return to activity as you feel better.
- ▶ Inform your physician about important changes in your lifestyle.
- ▶ Report side effects from medication immediately.
- ▶ Take the medication as recommended by your doctor - do not stop unless your doctor asks you to stop.
- ▶ Do not miss any follow-up appointments, including laboratory blood testing.

## 8.3. Medication

Your cardiologist may prescribe a number of blood thinning drugs to prevent blood clots from forming.

**A common treatment regimen will include:**

- ▶ Either clopidogrel or ticlopidine
- ▶ In combination with ASA (acetylsalicylic acid)

It is extremely important to follow your medication regimen.

If you stop taking the medication without your cardiologist's recommendation blood clots may form in your coronary arteries potentially leading to heart attacks or even death.



## 9. Glossary

### Angina pectoris

Angina pectoris commonly known as angina, is chest pain due to a lack of blood and hence oxygen supply to the heart muscle, generally due to obstruction or spasm of the coronary arteries. Coronary artery disease, the main cause of angina, is due to atherosclerosis of the coronary arteries. The term derives from the Greek ankhon ("strangling") and the Latin pectus ("chest"), and can therefore be translated as "a strangling feeling in the chest".

### Asymptomatic

In medicine, a disease is asymptomatic while the patient does not experience any noticeable symptoms. Asymptomatic diseases may not be discovered until the patient undergoes medical tests. Some diseases remain asymptomatic for a remarkably long time.

### Atherosclerosis

Atherosclerosis is a disease affecting arterial blood vessels. It is a chronic inflammatory response in the walls of arteries. It is commonly referred to as a "hardening" or "furring" of the arteries. It is caused by the formation of multiple plaques within the arteries. These plaque deposits lead to a restricted blood flow to the heart. Therefore, less oxygen and other nutrients reach the heart muscle. This may lead to angina pectoris or to a heart attack.

### Atheroma

In pathology, an atheroma is an accumulation and swelling in artery walls that is made up of cells or cell debris, that contain lipids (cholesterol and fatty acids), calcium and a variable amount of fibrous connective tissue. In the context of heart or artery matters, atheromata are commonly referred to as atheromatous plaques (please see plaque).

### Catheter (balloon or PTCA catheter)

In medicine a catheter is a tube that can be inserted into a body cavity, duct or vessel. Catheters thereby allow drainage or injection of fluids or access by surgical instruments. The process of inserting a catheter is catheterization. A balloon catheter is a type of "soft" catheter with an inflatable "balloon" at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body. The deflated balloon catheter is positioned, then inflated to perform the necessary procedure, and deflated again in order to be removed.

### Circulatory system

The circulatory system is extremely important for sustaining life. Its proper functioning is responsible for the delivery of oxygen and nutrients to all cells, as well as the removal of carbon dioxide and waste products, maintenance of optimum pH, and the mobility of the elements, proteins and cells of the immune system. In developed countries, the two leading causes of death, myocardial infarction and stroke each may directly result from an arterial system that has been slowly and progressively compromised by years of deterioration (see atherosclerosis).

### Computed tomography (CT)

Computed tomography is a medical imaging method employing tomography. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axis of rotation. The word "tomography" is derived from the Greek tomos (slice) and graphein (to write).

## Coronary artery disease (CAD)

CAD is also called coronary heart disease (CHD) or atherosclerosis, is the end result of the accumulation of atheromatous plaques within the walls of the arteries that supply oxygen and nutrients to the myocardium (the muscle of the heart). The restricted blood flow may lead to angina pectoris or a heart attack.

## Coronary angiography

Angiography or arteriography is a medical imaging technique in which an X-ray picture is taken to visualize the inner opening (lumen) of blood filled structures, including arteries, veins and the heart chambers. Its name comes from the Greek words angeion, "vessel", and graphien, "to write or record".

## Coronary angioplasty (PCI or PTCA)

Coronary angioplasty (also known as percutaneous coronary intervention, PCI or percutaneous transluminal coronary angioplasty, PTCA) is a therapeutic procedure to treat the stenotic (narrowed) coronary arteries of the heart found in coronary artery disease. Angioplasty is the mechanical widening of a narrowed or totally obstructed blood vessel. These obstructions are often caused by atherosclerosis. The word is composed of the medical combining forms of the Greek words ageios meaning "vessel" and plastos meaning "formed" or "moulded". Angioplasty is typically performed in a minimally invasive or percutaneous method.

## Coronary artery bypass graft surgery (CABG)

CABG also called heart bypass or bypass surgery is a surgical procedure performed to relieve angina and reduce the risk of death from coronary artery disease. Arteries or veins from elsewhere in the patient's body are grafted to the coronary arteries to bypass atherosclerotic narrowing and improve the blood supply to the coronary circulation supplying the myocardium (heart muscle).

## Contrast agent

Radiocontrast agents (also simply contrast agents or contrast materials) are compounds used to improve the visibility of internal bodily structures in an X-ray image.

## Electrocardiogram (ECG)

An electrocardiogram is a graphic produced by an electrocardiograph, which records the electrical activity of the heart over time. Its name is made of different parts: electro, because it is related to electronics, cardio, Greek for heart, gram, a Greek root meaning "to write".

## Fluoroscopy

Fluoroscopy is an imaging technique commonly used by physicians to obtain real-time images of the internal structures of a patient through the use of a fluoroscope. In its simplest form, a fluoroscope consists of an x-ray source and fluorescent screen between which a patient is placed.

## Hyperplasia (cell proliferation)

Hyperplasia is a general term referring to the proliferation of cells within an organ, vessel or tissue beyond that which is ordinarily seen in e.g. constantly dividing cells.

## Introducer sheath

A tube that is inserted into the body to provide an access point and allow the insertion of other instruments into the artery (e. g. a balloon catheter).

## Ischemia

In medicine, ischemia (Greek "isch-" is restriction, "hema or haema" is blood) is a restriction in blood supply, generally due to factors in the blood vessels, with resultant damage or dysfunction of tissue.

## Lesion

A lesion is any abnormal tissue found on or in an organism, usually damaged by disease or trauma. Lesion is derived from the Latin word *laesio* which means injury.

## Lumen

A lumen (pl. lumina) is an inner space, lining or cavity. In case of vascular procedures it describes the inner opening of the blood vessel.

## Magnetic resonance imaging (MRI)

Magnetic resonance imaging (MRI) is primarily used in medical imaging to visualize the structure and function of the body. It provides detailed images of the body in any plane. MR has much greater soft tissue contrast than computed tomography (CT) making it especially useful in neurological, musculoskeletal, cardiovascular, and oncological imaging. Unlike CT it uses no ionizing radiation, but uses a powerful magnetic field to align the magnetization of hydrogen atoms in the body. Radio waves are used to systematically alter the alignment of this magnetization, causing the hydrogen atoms to produce a rotating magnetic field detectable by the scanner. This signal can be manipulated by additional magnetic fields to build up enough information to reconstruct an image of the body.

## Medication

Medication is a medicine, drug or other substance used to prevent or cure disease or to relieve pain.

## Myocardial infarction (MI)

MI more commonly known as a heart attack, is a medical condition that occurs when the blood supply to a part of the heart is interrupted, most commonly due to rupture of a vulnerable plaque. The resulting ischemia or oxygen shortage causes damage and potential death of heart tissue. It is a medical emergency, and the leading cause of death for both men and women all over the world.

## Percutaneous

Percutaneous pertains to any medical procedure where access to inner organs or other tissue is done via needle-puncture of the skin, rather than by using an "open" approach where inner organs or tissue are exposed. The percutaneous approach is commonly used in vascular procedures. This involves a needle catheter getting access to a blood vessel, followed by the introduction of a wire through the lumen of the needle. It is over this wire that other catheters can be placed into the blood vessel. This technique is known as the modified Seldinger technique.

## Plaque

Plaque is an accumulation or buildup of cholesterol, fatty deposits, calcium and collagen in a coronary vessel that leads to blockages in the blood vessel (also atheroma or atheromatous plaque).

## Platelets

Platelets, or thrombocytes, are the cells circulating in the blood that are involved in the cellular mechanisms of primary hemostasis leading to the formation of blood clots (or thrombus).

## Restenosis (In-stent restenosis – ISR)

Restenosis literally means the reoccurrence of stenosis. This is usually restenosis of an artery, or other blood vessel, that has been "unblocked". This term is common in all branches of medicine that frequently treat stenotic lesions (e. g. interventional cardiology following angioplasty).

## Risk factor

A risk factor is a variable associated with an increased risk of disease or infection. Risk factors are evaluated by comparing the risk of those exposed to the potential risk factor to those not exposed; i.e. number of persons experiencing the event divided by the number of persons exposed to the risk factor.

## Seldinger technique

The Seldinger technique is a medical procedure to obtain a safe access to blood vessels and other hollow organs. It is named after Dr. Sven-Ivar Seldinger (1921–1998), a Swedish radiologist from Mora, Dalarna County, who introduced the procedure in 1953.

## Stenosis

A stenosis is an abnormal narrowing in a blood vessel or other tubular organ or structure.

## Stent (coronary stent, bare metal stent, drug-eluting stent)

In medicine, a stent is a tube that is inserted into a natural conduit of the body to prevent or counteract a disease-induced localized flow constriction. The most widely known stent use is in the coronary arteries with a bare metal stent, a drug-eluting stent or occasionally a covered stent. A drug-eluting stent is a coronary stent (a scaffold) that slowly releases a drug to block cell proliferation.

## Symptom

A symptom is a manifestation of a disease, indicating the nature of the disease, which is noticed by the patient.

## Symptomatic

In medicine, a disease is symptomatic when it is at a stage when the patient is experiencing symptoms.

## Thrombosis

Thrombosis is the formation of a clot or thrombus inside a blood vessel, obstructing the flow of blood through the circulatory system.

## Thrombus

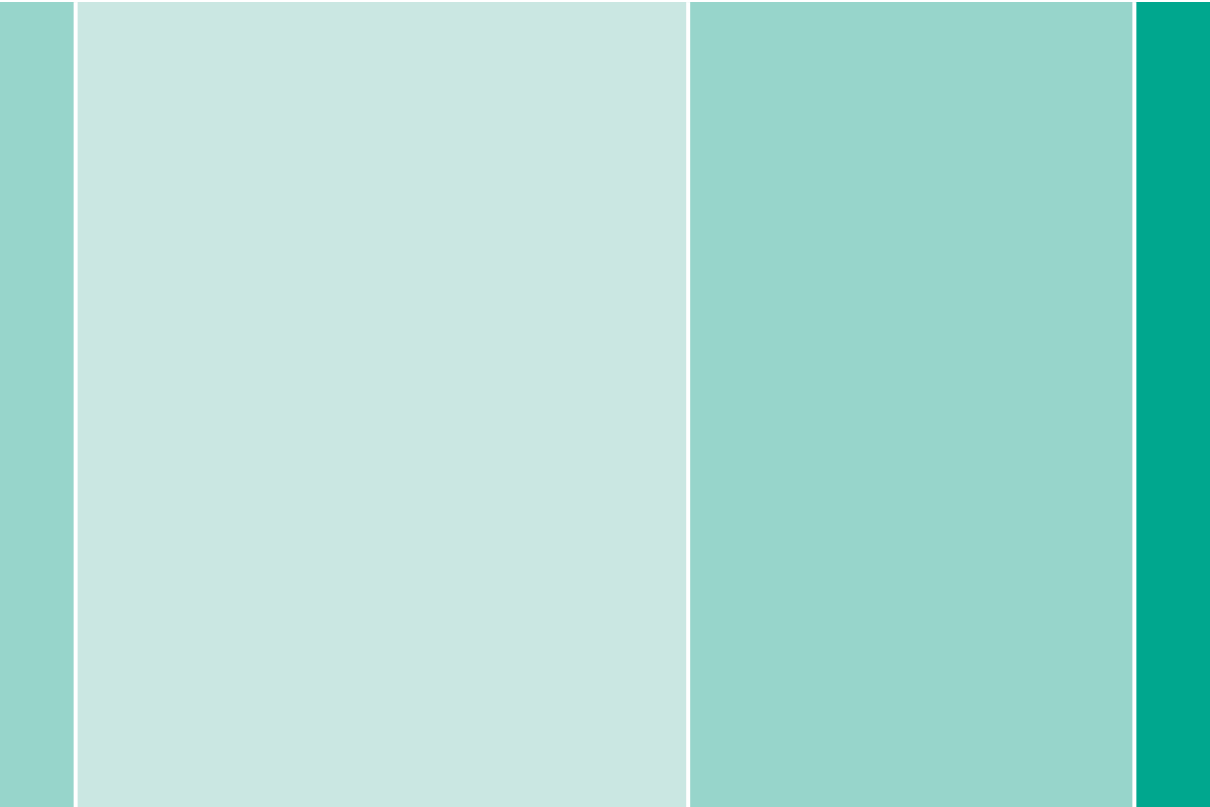
A thrombus, or blood clot, is the final product of the blood coagulation step in hemostasis. It is achieved via the aggregation of platelets that form a platelet plug, and the activation of the humoral coagulation system (i.e. clotting factors).

## X-Ray

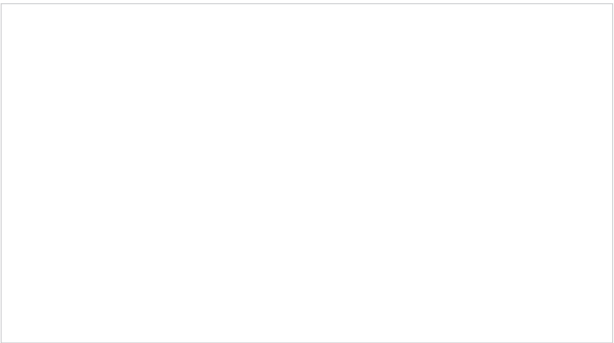
An X-ray (or Röntgen ray) is a form of electromagnetic radiation. The x-rays are longer than Gamma rays but shorter than UV rays. X-rays are primarily used for diagnostic radiography and crystallography. X-rays are a form of ionizing radiation and as such can be dangerous. In many languages it is called Röntgen radiation after one of the first investigators of the X-rays, Wilhelm Conrad Röntgen.



## Notes



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