



NAME

Greenfield Ben

MRN



Cleverly ID Number

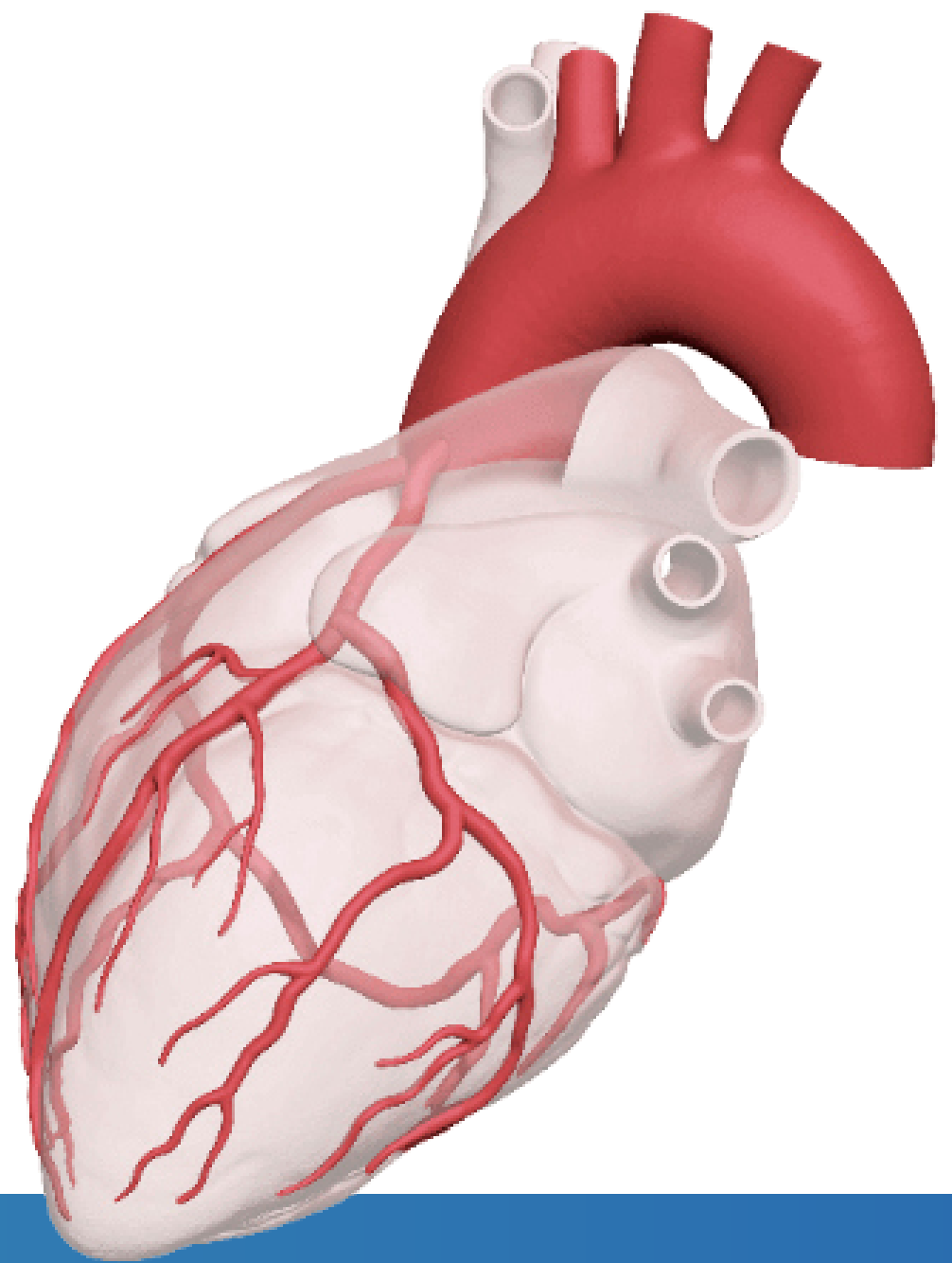


Date of Examination

11/30/2023 09:49 AM

Healthcare Provider

SHAH DARSHAN



Greenfield Ben, Let's Examine Your Heart

Section

01

Know The Problem: Coronary Artery Disease

02

Know Your Risk: Heart Attack Risk Factors

03

Know Your Test: What Does the Cleverly Analysis See?

04

Know Your Heart: Detailed Cleverly Analysis

Why Cleerly?

Cleerly was designed to support you and your healthcare professional in addressing the following:

Did You Know?

One-third of all deaths are due to cardiovascular disease, making it the #1 killer of both men and women worldwide, and taking a life prematurely every 2 seconds.¹

Do You Have Disease?

Symptoms such as chest pain or shortness of breath are not reliable assessments of disease. More than half of people will feel no symptoms before experiencing their first heart attack.²

Protect Your Heart

90% of heart attacks are estimated to be preventable but you can't prevent what you can't see Cleerly.³



01 Know The Problem: Coronary Artery Disease

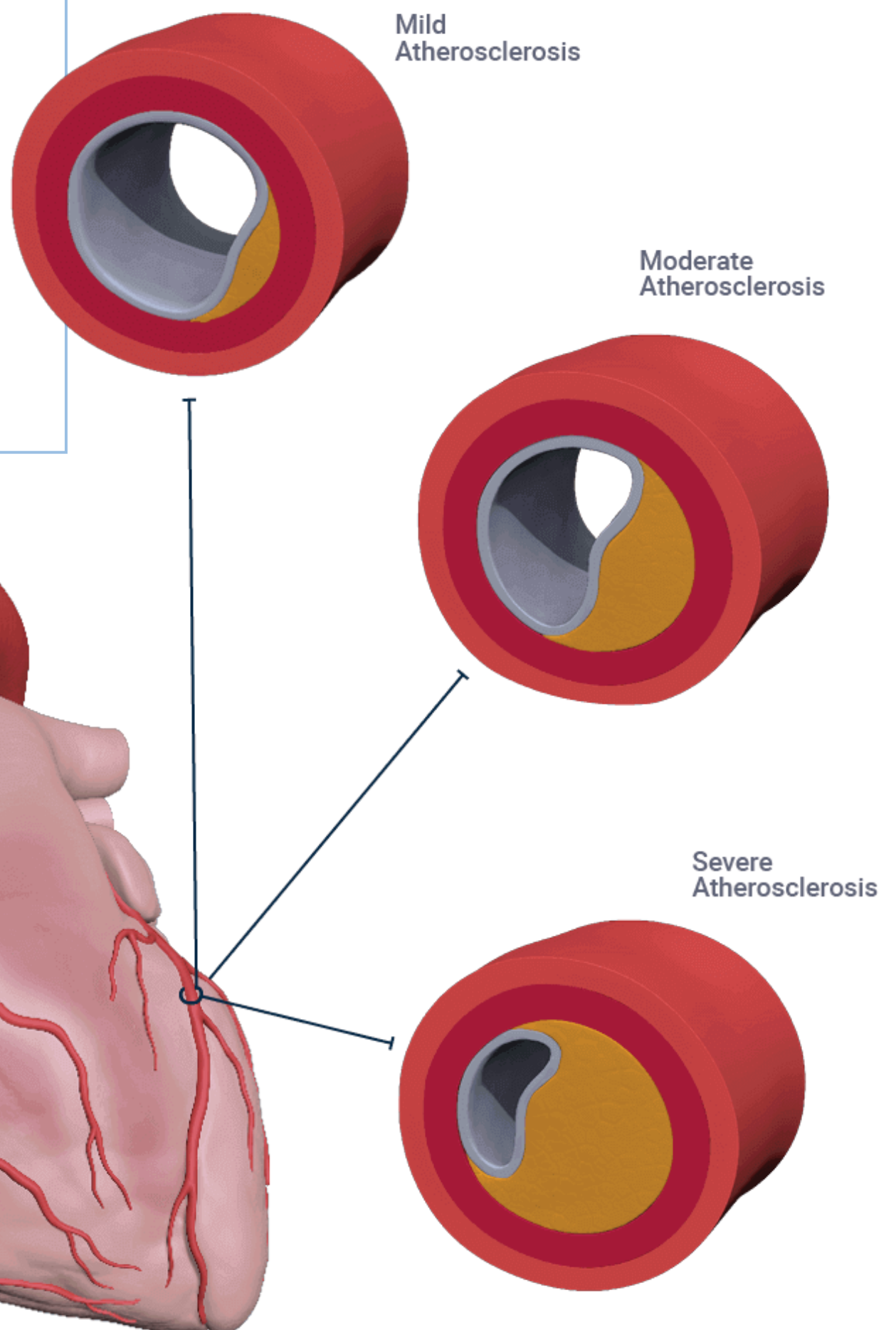
What is coronary artery disease?

Coronary artery disease (CAD) is a form of cardiovascular disease that develops when atherosclerosis (plaque) builds up in the walls of coronary arteries and causes one or more coronary arteries to narrow, a typically silent process that occurs over decades.

If the plaque grows, it can cause stenosis (narrowing) of the coronary artery.

In severe cases, the combination of plaque and narrowing may reduce blood flow, limiting the supply of oxygen-filled blood to the heart. This is called ischemia. People with ischemia sometimes have chest pain, shortness of breath or other symptoms.

Atherosclerosis (plaques) can build up in the arteries over several decades. Depending on the type of plaque, this can lead to a narrowing of the artery and/or a plaque rupture which can cause a cardiovascular event (heart attack).



The figure to the right illustrates the 3 stages of coronary artery disease progression. Plaque build up is illustrated in orange:

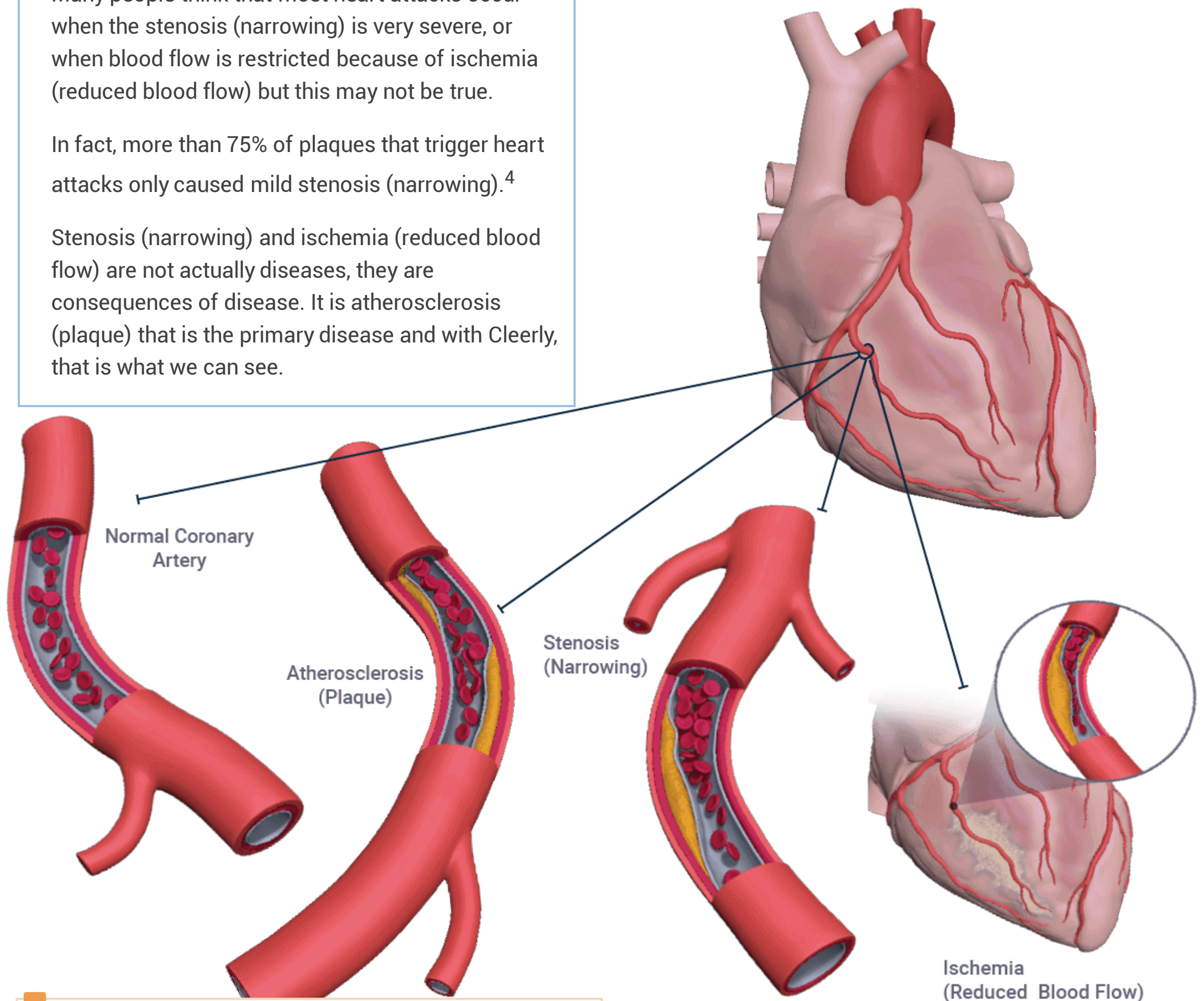
Know The Problem: Coronary Artery Disease

What causes a heart attack: atherosclerosis (plaque), stenosis (narrowing of the artery) or ischemia (reduced blood flow)?

Many people think that most heart attacks occur when the stenosis (narrowing) is very severe, or when blood flow is restricted because of ischemia (reduced blood flow) but this may not be true.

In fact, more than 75% of plaques that trigger heart attacks only caused mild stenosis (narrowing).⁴

Stenosis (narrowing) and ischemia (reduced blood flow) are not actually diseases, they are consequences of disease. It is atherosclerosis (plaque) that is the primary disease and with Cleerly, that is what we can see.



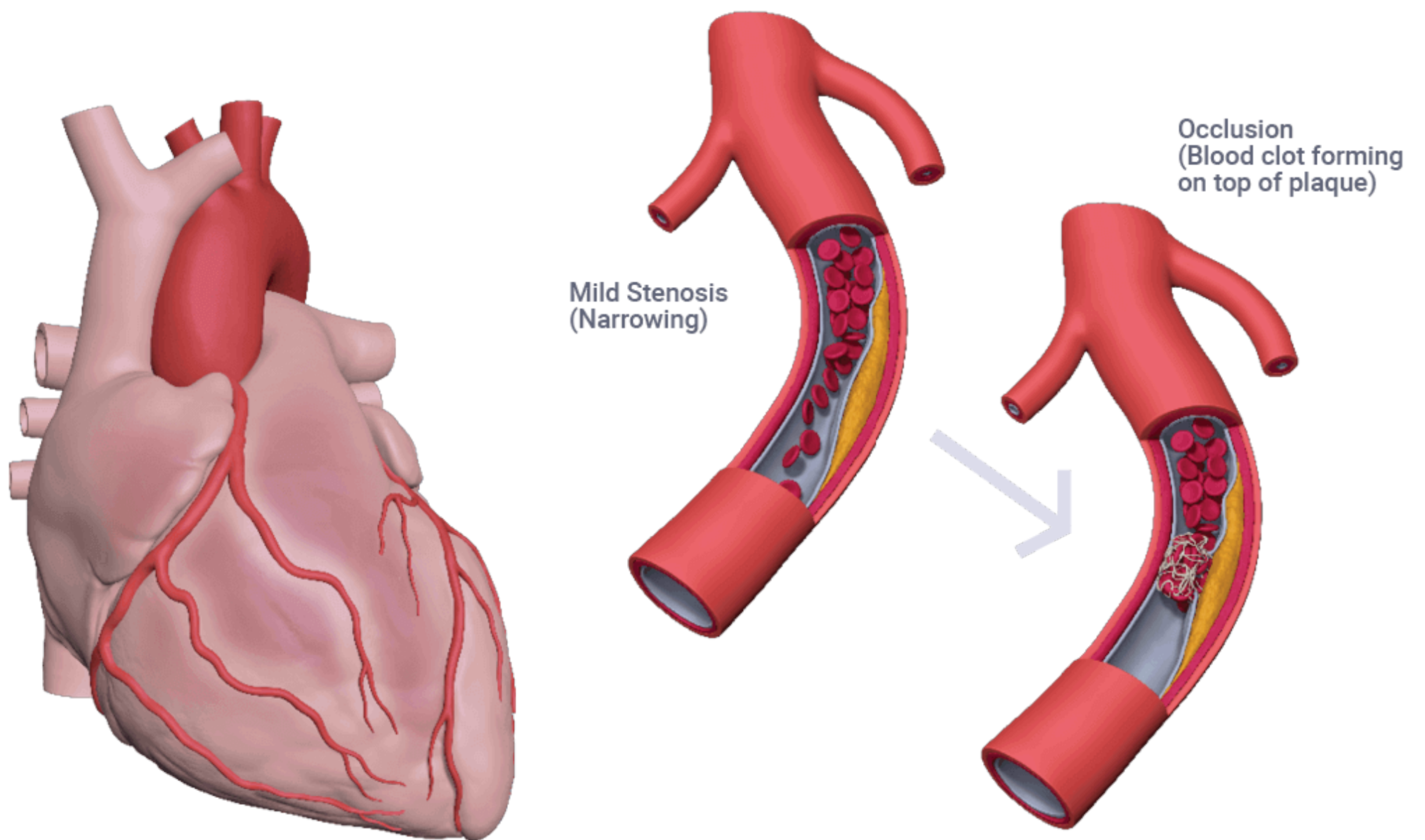
Plaque that cause only mild stenosis (narrowing) at the time of their evaluation. Since you can't "feel" this disease, you need to see it Cleerly cardiovascular event (heart attack).

Know The Problem: Coronary Artery Disease

How can atherosclerosis (plaques) that cause only mild narrowings trigger heart attacks?

Plaques that cause heart attacks typically associated with only mild narrowing of the heart artery at the time of their evaluation. These plaques are filled with cholesterol contents and are covered by a very thin “cap” that may rupture or erode into the blood stream, exposing its contents to the blood in the heart artery. When this ensues, a blood clot may form around the ruptured site that can block (occlude) the artery. If 100% occlusion occurs, blood cannot flow normally through the artery, and a heart attack occurs.

Because most atherosclerosis (plaques) that cause heart attacks cause only mild narrowings at the time of their evaluation, most people will have no symptoms before suffering a heart attack, making coronary artery disease the largest “silent” killer of men and women in the world.



Know The Problem: Coronary Artery Disease

Are all plaques the same?

No, atherosclerosis (plaques) can differ significantly between people, and even within the same person, many different types of plaques can be present.

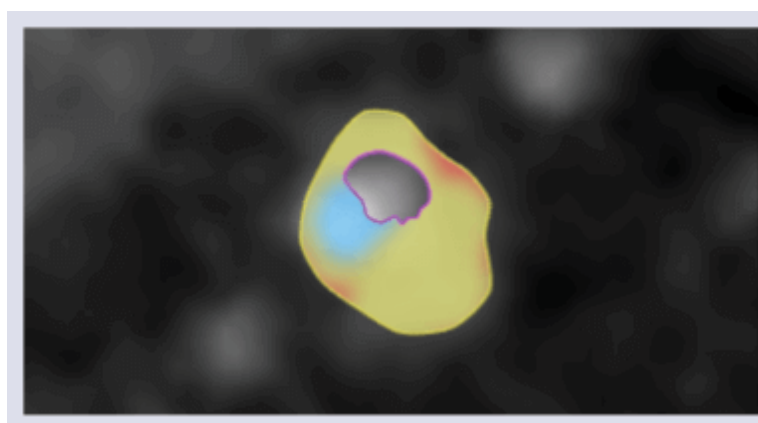
Some plaques are very stable and rarely cause heart attacks, while others are higher risk and are often more implicated as the cause of heart attacks.

Plaques can differ by their amount (volume), makeup (composition), location, focality, morphology (direction of growth outward versus inward growth) and length. All of these factors may play a very important role in your risk of experiencing a heart attack.

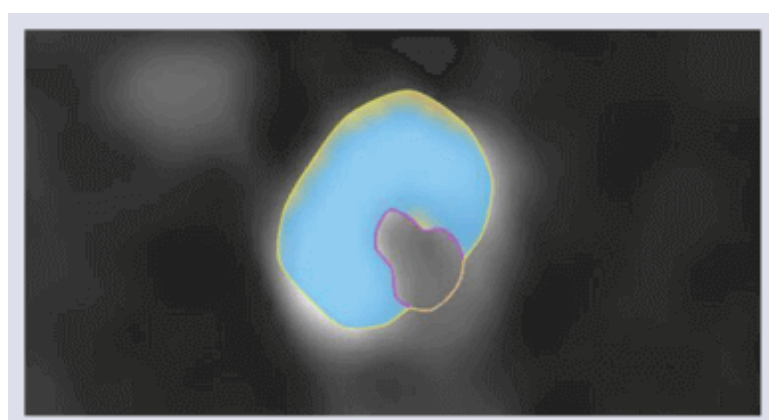
Many heart attacks occur in the absence of any symptoms when the stenoses (narrowings) are mild but when higher risk atherosclerosis (plaque) features may be present.

These figures illustrate a cross-section of different atherosclerosis (plaque) types.

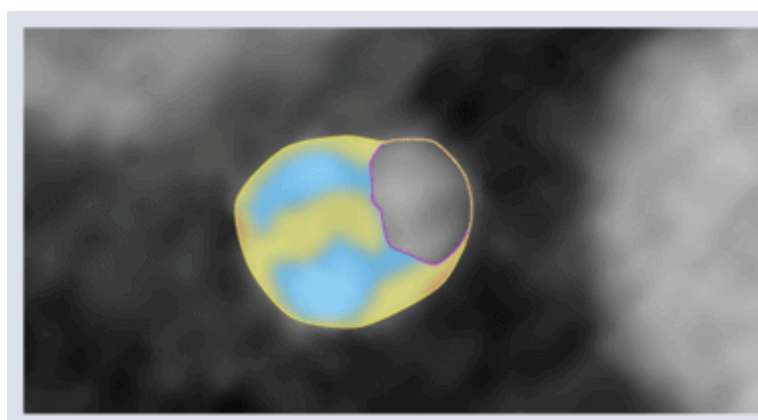
All Plaque Types



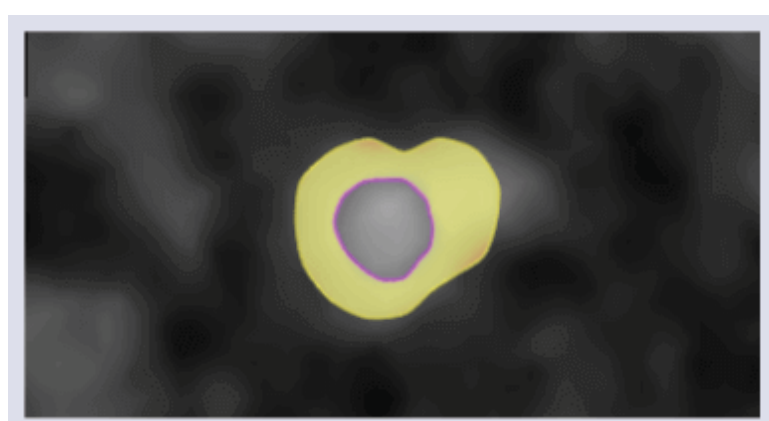
Calcified Plaque (blue)



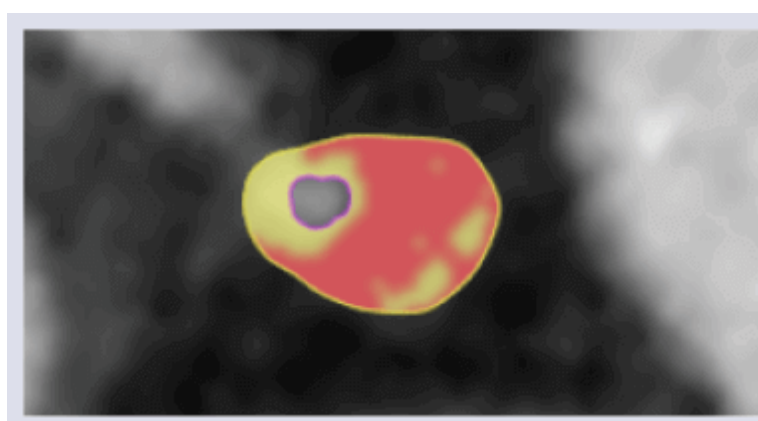
Non-Calcified (yellow) and Calcified Plaque (blue)



Non-Calcified Plaque (yellow)



Low-Density–Non-Calcified Plaque (red)

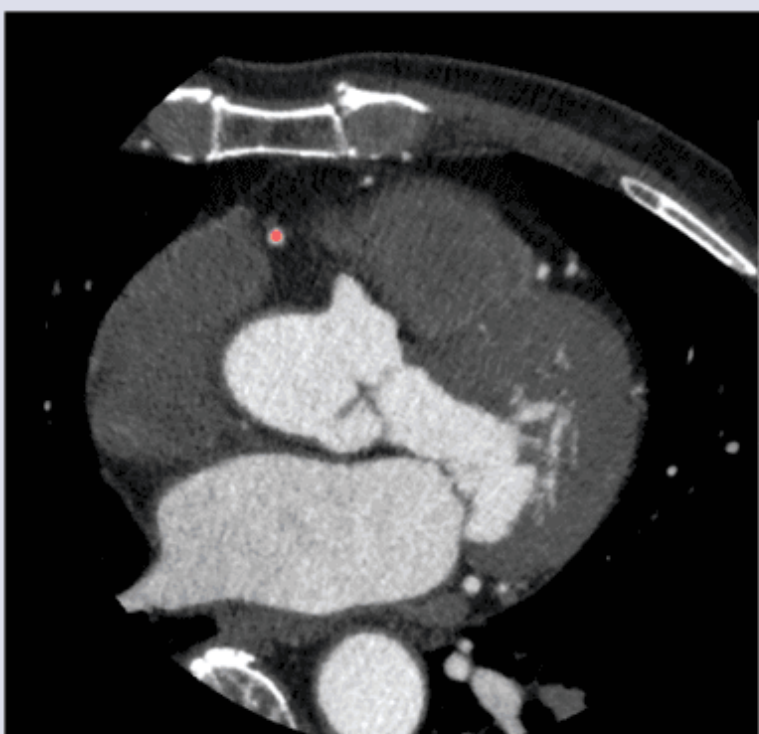


Know The Problem: Coronary Artery Disease

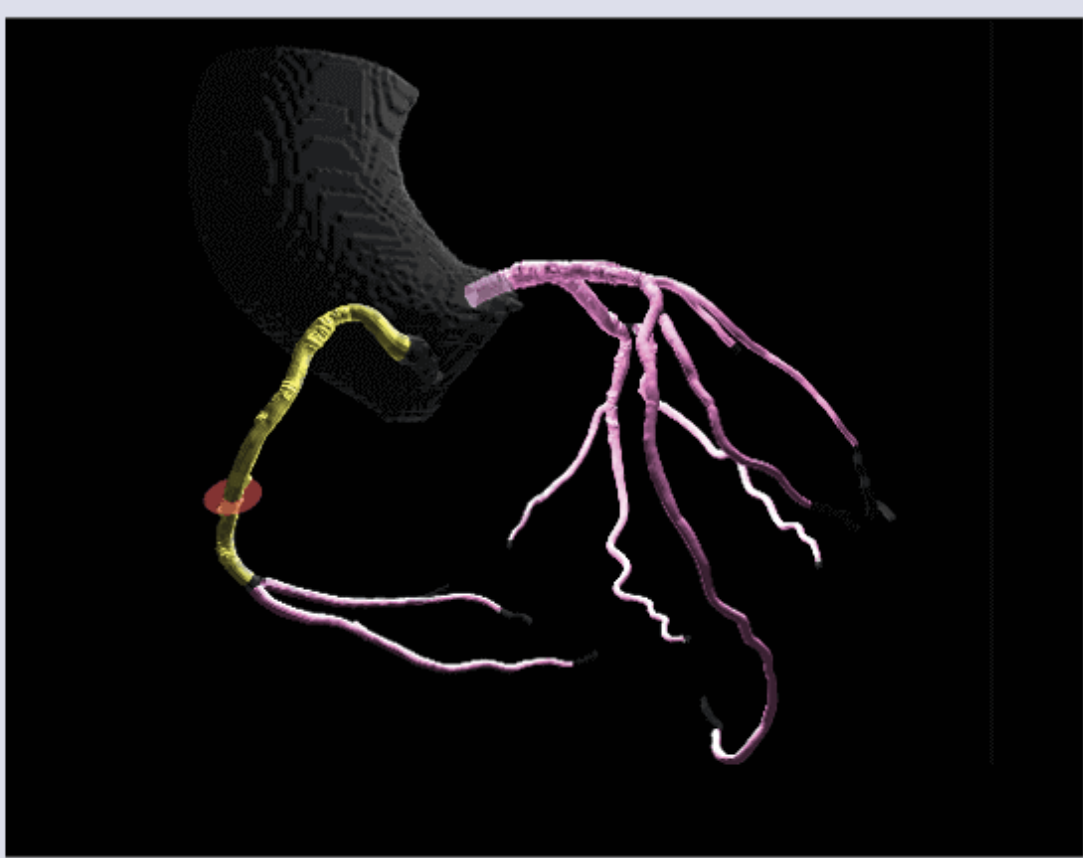
How do you differentiate “higher risk” plaques from potentially more “stable” plaques?

Heart specialists know that there is no single way to determine which plaque is going to cause a heart attack. But findings that may increase the risk of a heart attack can be visualized using advanced imaging with the Cleerly analyses.

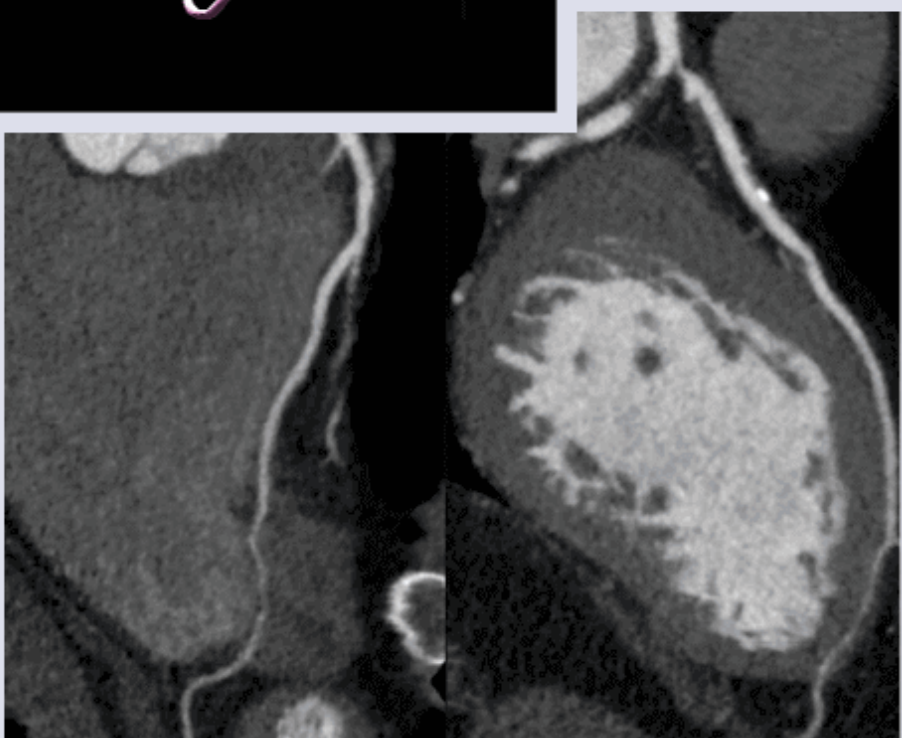
Coronary CT angiography, or advanced “cat scans” of the heart arteries, are the most accurate non-invasive method to quantify and characterize atherosclerosis (plaques). It is the test of choice for evaluation of suspected coronary artery disease in many professional societal guidelines. ^{5,6,7}



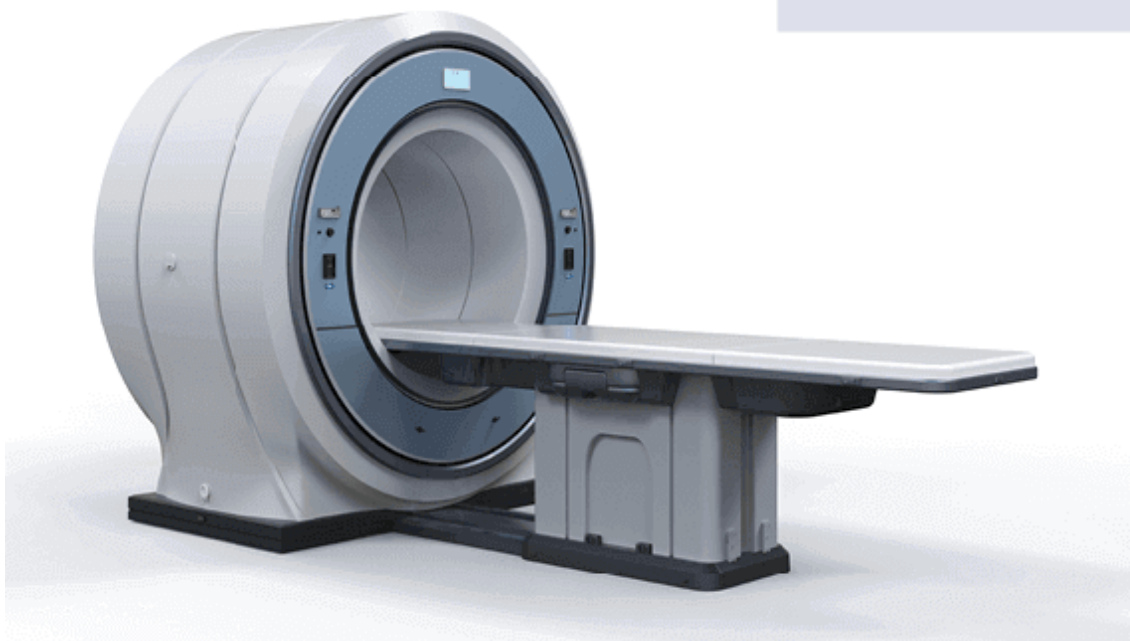
The figure above illustrates a cross-section of the heart.



The figure above depicts coronary arteries that have been extracted and illustrated in 3D.



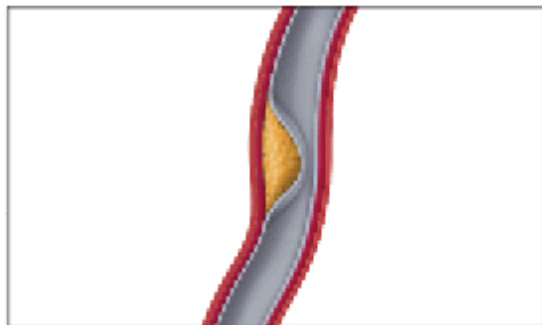
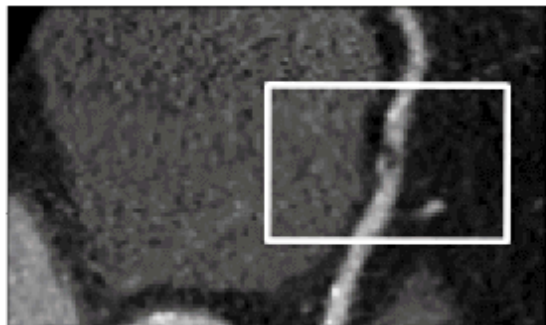
The figure above illustrates 2 images of the same coronary artery in the heart depicted in different views.



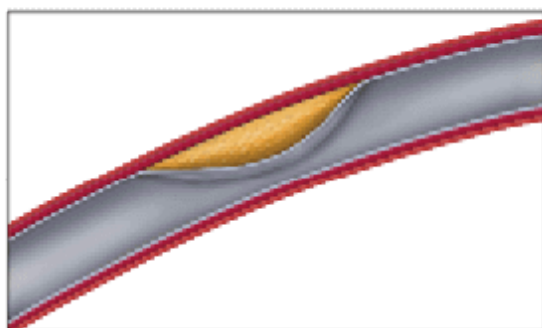
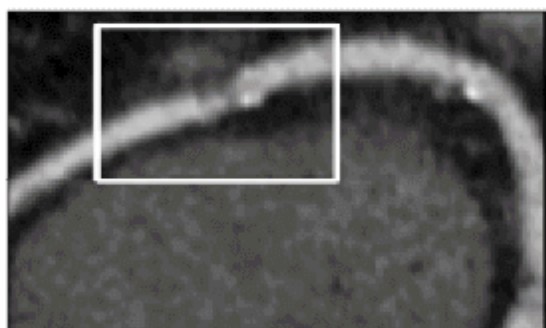
Know The Problem: Coronary Artery Disease

What are the "higher risk" features that the CT can see?

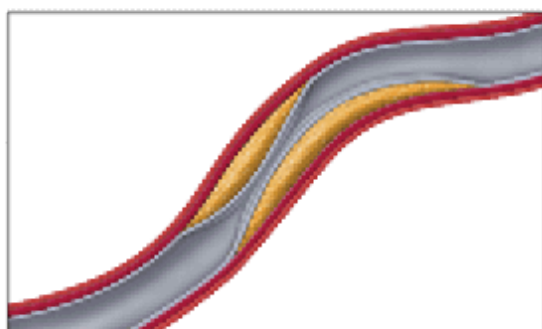
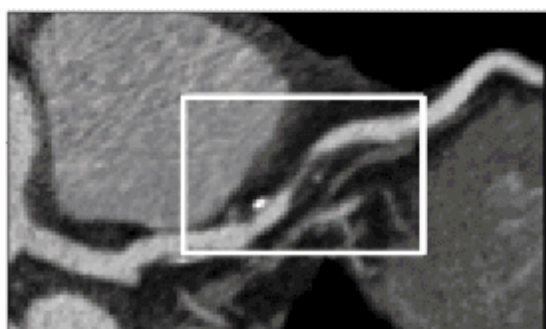
Findings that may increase risk of a heart attack include:



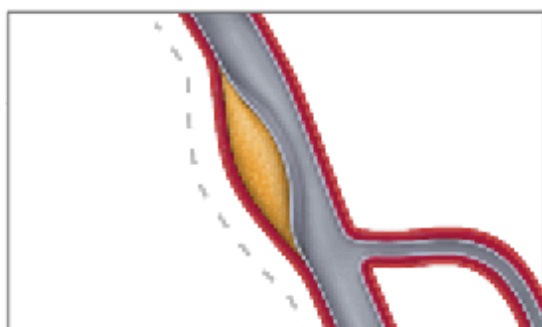
Plaque Volume: Atherosclerosis (plaque) volume is the amount of plaque that has built up in the walls of heart arteries, and may be an indicator of the risk of future heart attack over the course of your life.^{8,9}



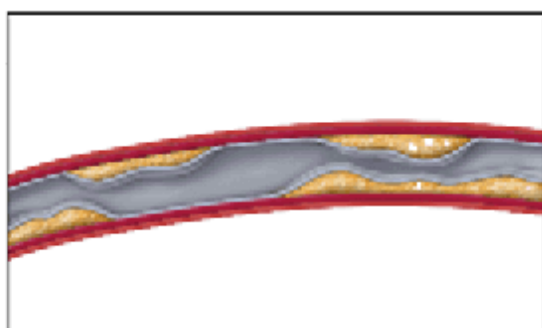
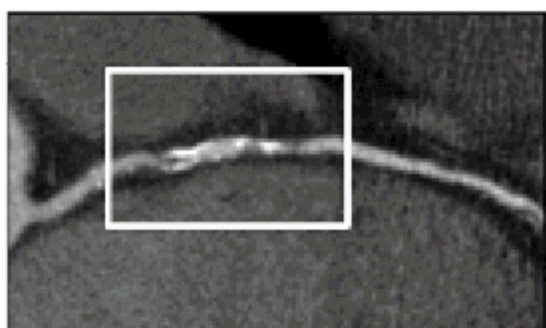
Plaque Composition: On CT scans, darker (lower density), non-calcified plaques possess higher cholesterol concentrations and may be associated with a higher risk of heart attacks than brighter, calcified plaques.^{4,10}



Narrowing of the Arteries: When plaques cause severe narrowing of more than 50% of the inner portion of the artery—a condition known as severe stenosis—they may be at higher risk of causing heart attacks.⁸



Outward Growth of Plaque: These plaques have been associated with heart attacks when they also have low-density - non-calcified plaque.¹¹



Impaired Blood Flow: When plaques that cause stenosis (narrowings) limit the blood flow within an artery—a condition known as ischemia—they may be at higher risk of causing heart attacks.¹²

One important fact to note is that atherosclerosis (plaque) is a dynamic process, and these "higher risk" features of atherosclerosis (plaque) may be changed over time with effective medical therapy and lifestyle modification.¹³

Know The Problem: Coronary Artery Disease

How do I get rid of my atherosclerosis (plaque)?

For this question, there is both good news and bad news:

Good News:

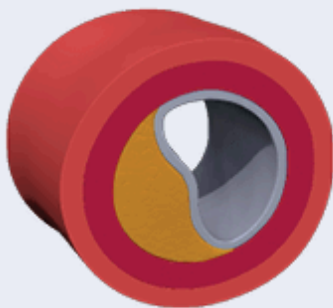
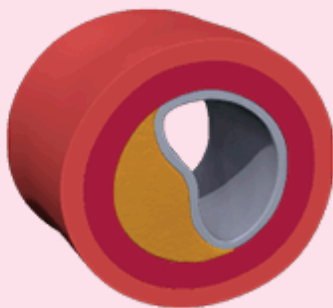
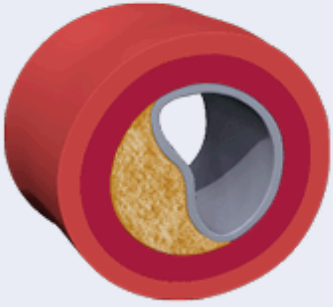
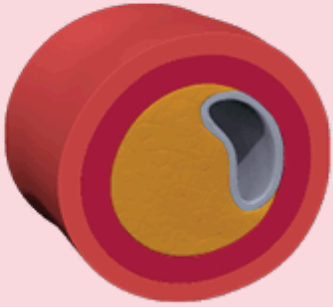
The good news is that, even if you do have atherosclerosis (plaques), many medicines and lifestyle modifications can favorably transform this plaque over time, significantly reducing your risk of a heart attack.¹⁴

Bad News:

Once atherosclerosis (plaque) builds up, it is rare for it to actually disappear, or regress.

Your Goal:

The primary goal of your treatment is to stabilize atherosclerosis (plaques) to decrease your chances of experiencing a heart attack. Stabilization can be accomplished in many ways and may occur by slowing progression, transforming the composition, and reducing higher risk plaque features.¹⁴ Many medicines and lifestyle modifications are available to help you accomplish this, and you should speak to your doctor about the best approach for your personal case.

	On Statins	Not on Statins
Baseline		
At Follow Up		
Outcome	<p>Plaque stabilization:</p> <ul style="list-style-type: none"> • Reduced plaque progression • Reduced 'higher risk' plaque features, such as low density–non-calcified plaque or positive remodeling 	<p>Increased heart attack risk:</p> <ul style="list-style-type: none"> • Persistent plaque progression • Persistence of 'higher risk' plaque features

Above are changes that occur in patients who take statin medications—a common treatment for coronary atherosclerosis (plaque)—compared to patients who do not take statin medication.

02 Know Your Risk: Heart Attack Risk Factors

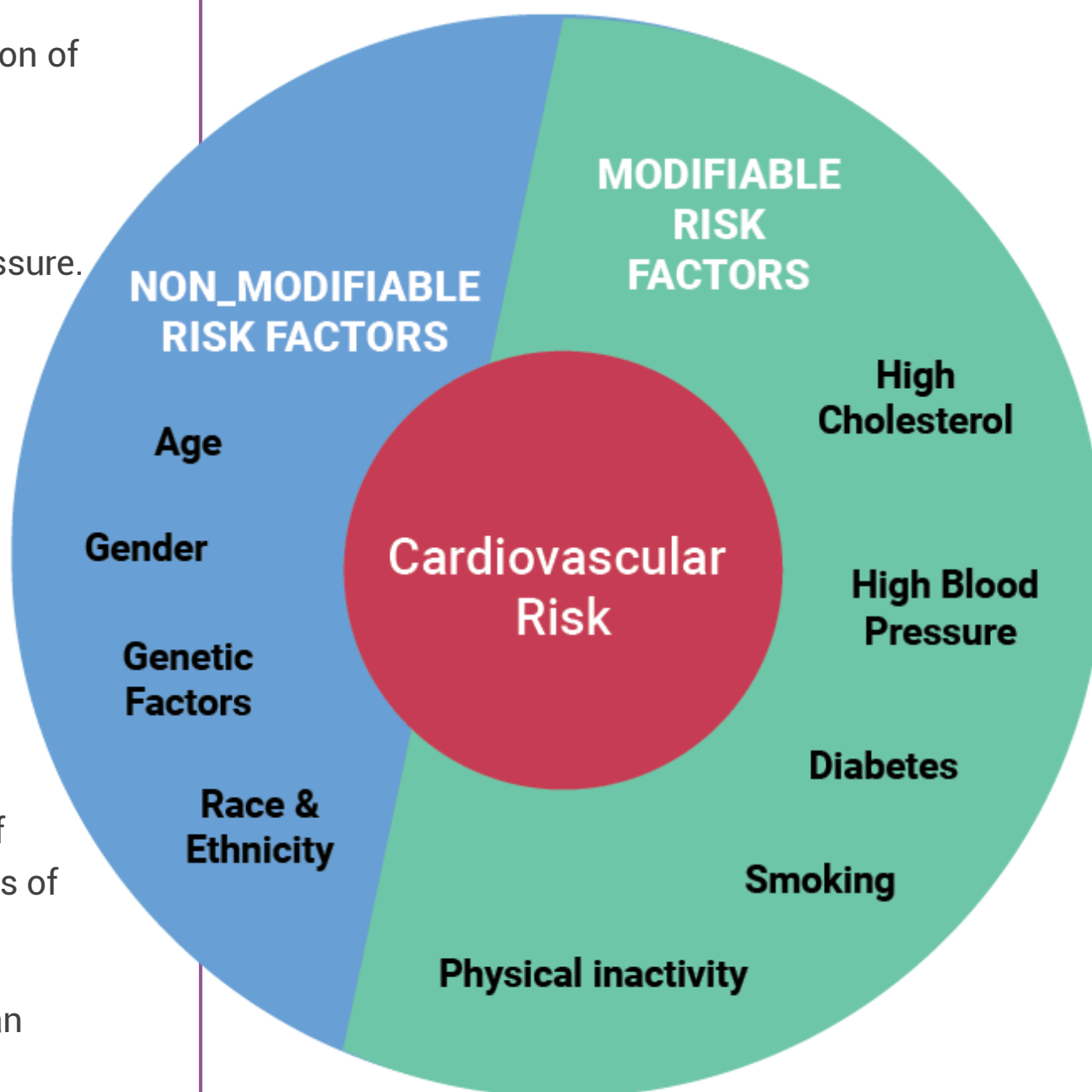
How can I assess my risk of heart attack?

At present, early diagnosis of coronary artery disease is generally performed by assessing a patient's risk factors.

Some of these risk factors cannot be modified, such as gender and advancing age. The good news is that many risk factors may be successfully managed through healthy lifestyles, such as improvements in diet, increases in physical activity, and cessation of tobacco use. Other risk factors can be successfully managed through medical therapy, such as treatments for high cholesterol, diabetes, and high blood pressure.

There are 3 important facts that you should be aware of when relying upon heart disease risk factors to determine your risk of heart attack:

1. Risk factors work better for comparing populations (groups) of people than for pinpointing a person's individual risk.
2. Risk factors are surrogate measures of heart disease, rather than direct measures of heart disease.
3. Risk factors may not effectively track an individual's heart disease progression or effectiveness of medical therapy over time.



Know Your Risk: Heart Attack Risk Factors

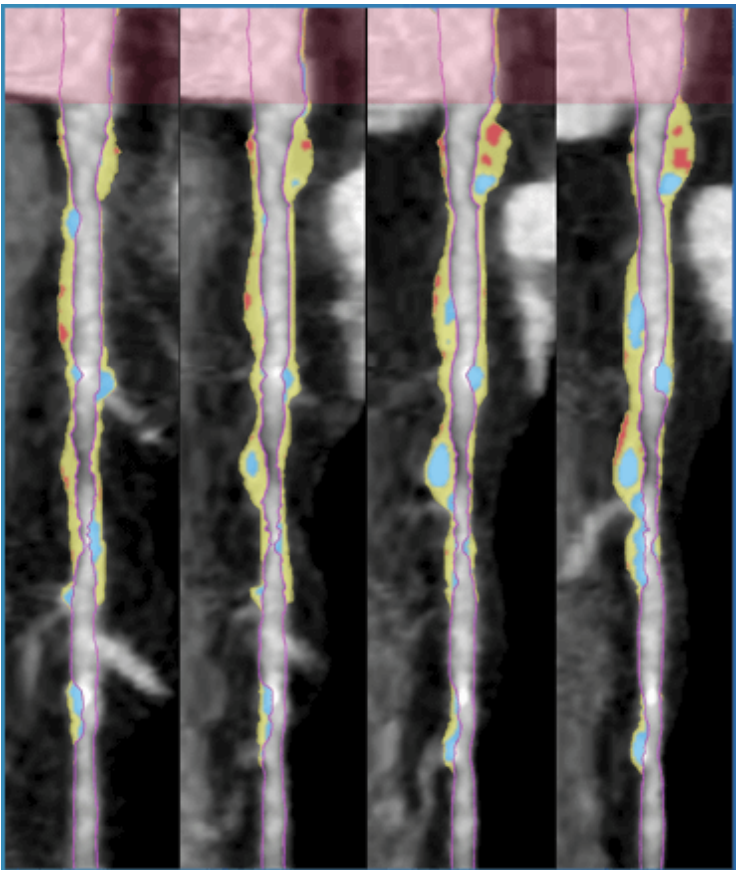
The Problem with Surrogate Measures of Heart Disease

Risk factors—such as cholesterol levels—are surrogate, indirect measurements of heart disease that may not necessarily have a guaranteed relationship to heart disease.

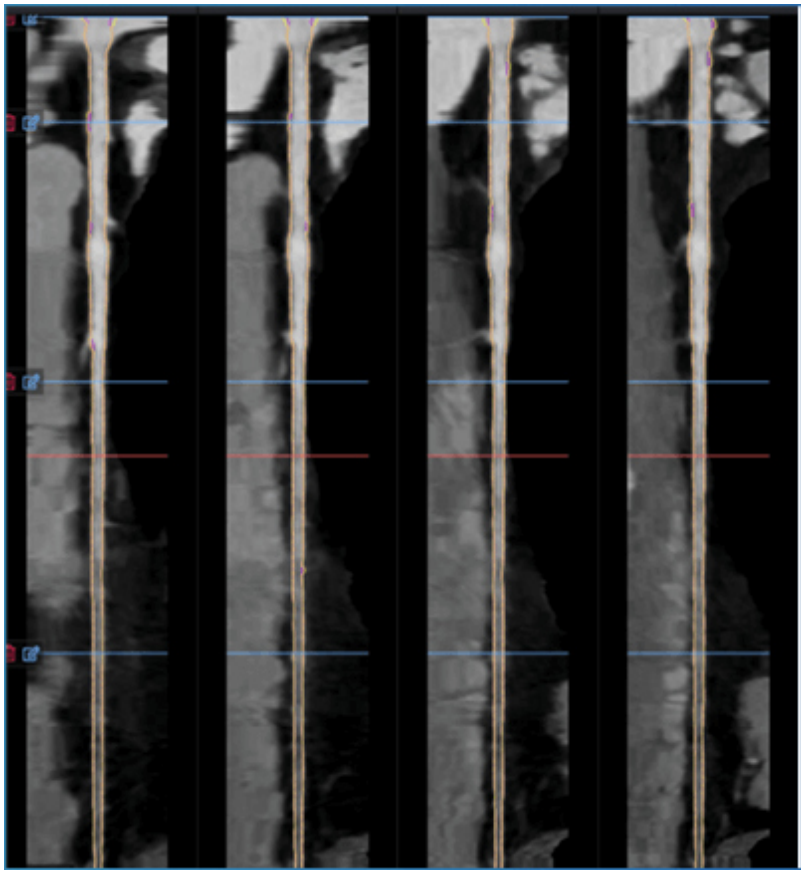
If risk factors do not correlate to actual heart disease, 2 issues may arise:

1. Risk factors may erroneously categorize a person as being at high risk of disease when they actually do not have any disease. This may lead to treatments with unnecessary medications that have high cost and significant side effects.
2. Risk factors may unwittingly identify a person as having a low risk of disease, but that person may actually have severe disease and be unaware of it.

Let's take a look at 2 hypothetical patients below who illustrate these concepts:



Mrs. S is 50 year old woman with no traditional risk factors. She feels fine and jogs regularly. Her Clearly analysis demonstrates severe plaque build up. These findings may be associated with an increased risk of future heart attacks.



Mr. J is 50 year old man with high blood pressure, elevated cholesterol and early signs of diabetes. He's symptom free but does not exercise regularly. His Clearly analysis shows no plaque in his heart arteries, a finding that may be associated with a low risk of future heart attacks.

Mrs. S and Mr. J illustrate the discordances that may occur by relying on traditional risk factors when direct visualization of the heart arteries may offer more information related to quantification and characterization of heart disease.

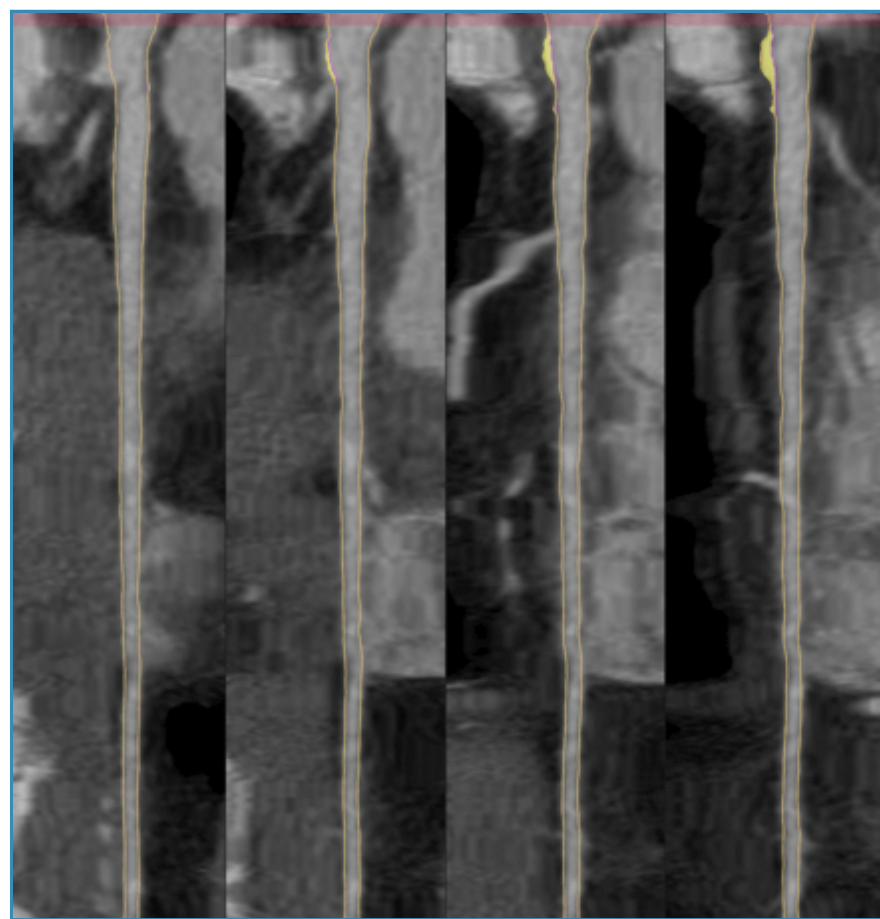
Know Your Risk: Heart Attack Risk Factors

How do I track my disease over time?

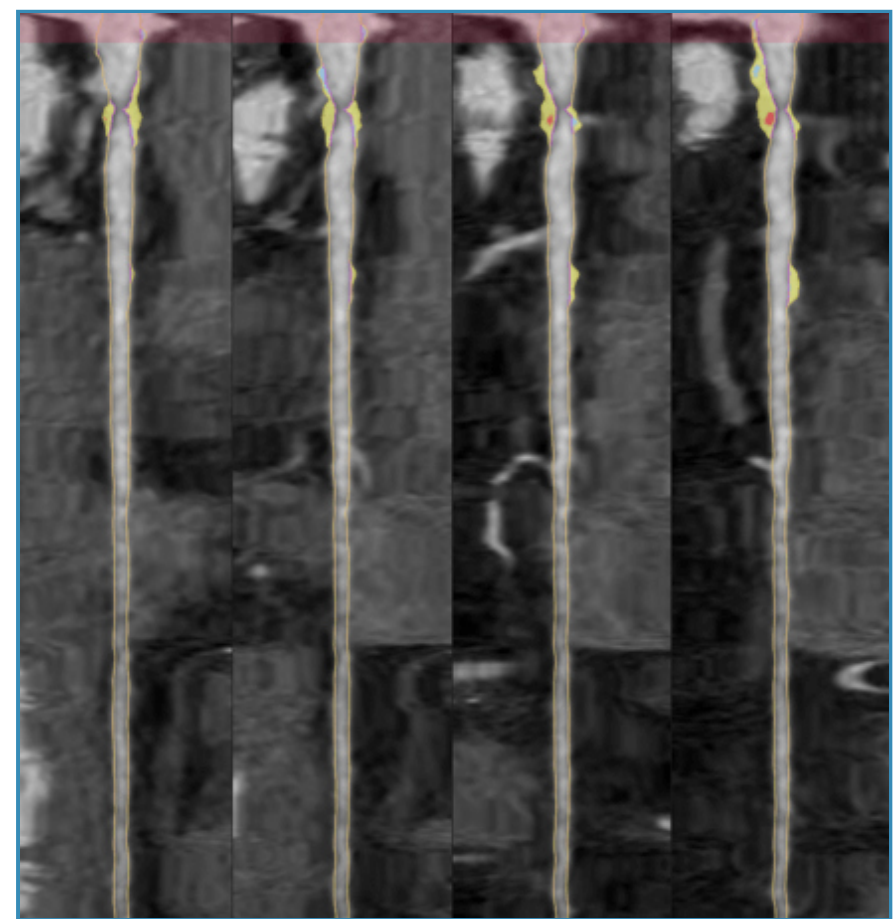
One approach is to develop a plan with your practitioner to reduce your risk, and then have follow up testing to make sure you're on the right track. Controlling risk factors with medications or lifestyle changes is the current method used by healthcare providers to consider a person's risk of heart attacks over time but this method comes with limitations and may not work in everyone.

As an example, populations of people who are indicated to take statin medications to lower their cholesterol experience a significant reduction in heart attack rates by about 25%. While this makes statin medications very effective for the prevention of heart attacks, it also underscores the approximately 75% of the "forgotten majority" of people who do not benefit.¹⁵ By simply checking cholesterol levels over time, we cannot fully know which individual patients are benefitting or not from statin therapy. Another approach for following someone's heart disease progression over time may be through direct visualization of their heart arteries by advanced CT imaging.

Let's take a look at a hypothetical patient below who illustrates this concept:



Baseline



Follow up

Mrs. R is 50 year old woman with high cholesterol. She was started on a statin medication, and her cholesterol was lowered into an acceptable range. She experiences no symptoms, and is compliant with her medications, diet and physical activity.

As can be seen by the study above, despite being treated with statin medications and successfully lowering her cholesterol, **Mrs. R** experiences significant disease progression of her heart disease with the development of large amount of plaque highlighted in yellow, red and blue in the above follow-up image. In consultation with her physician, **Mrs. R** began to take a 2nd medication in hopes of better controlling her disease.

Know Your Risk: Heart Attack Risk Factors

Is there a single measure that can integrate all of an individual's risk factors?

As you can see, heart disease can be very complex with many factors contributing to it. One way to integrate the many factors that contribute to heart disease is to personalize the evaluation to the individual patient by evaluating coronary artery risk markers through advanced CT scans.^{1,6}

Medical imaging by advanced CT scans can quantify and characterize the actual amount and type of plaque buildup within an individual's heart arteries over the course of their life. This approach will provide a single unified marker to determine the entire contribution of risk factors to actual heart disease.

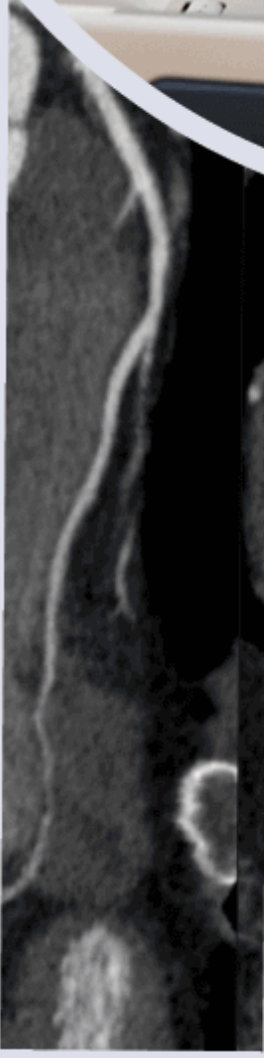


Non-Modifiable Risk Factors

- Age
- Gender
- Genetic Factors
- Race & Ethnicity

Modified Risk Factors

- High Cholesterol
- High Blood Pressure
- Diabetes
- Smoking
- Physical inactivity



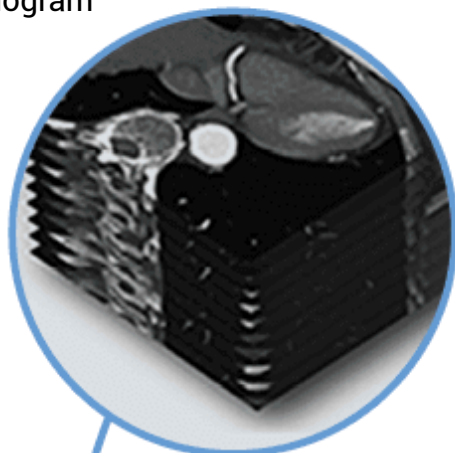
03 Know Your Test: What Does the Cleerly Analysis See?

Cleerly is a State-of-the-Art Artificial Intelligence (AI) Solution

The Cleerly analysis uses advanced artificial intelligence and deep learning frameworks to help quantify and characterize heart disease in a way not achievable even a few years ago.

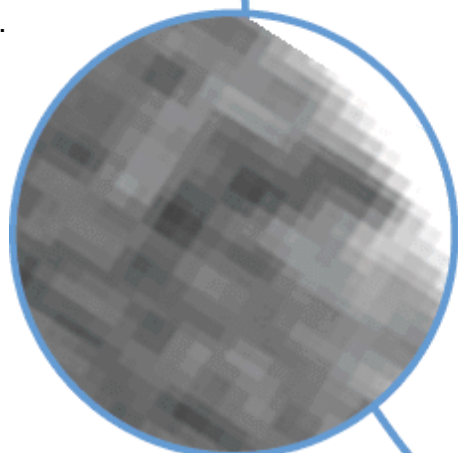
Image Acquisition

A non-invasive CT angiogram is performed.



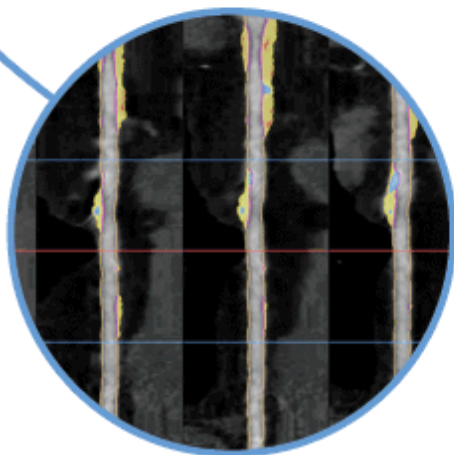
Sub-Voxel Resolution

Cleerly finds information in the pixels of your heart images that cannot be easily appreciated by the naked eye.



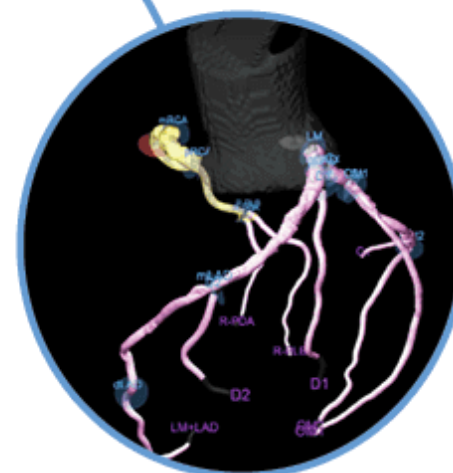
Artery Identification

Cleerly's algorithms extract your arteries from the volume of data within the CT image.



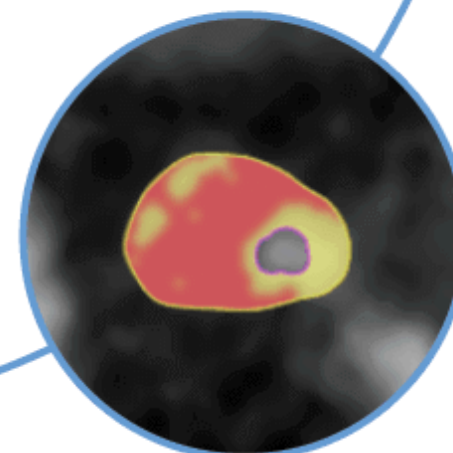
Advanced Data Curation

Cleerly integrates the data and provides you and your healthcare provider with vital information related to coronary artery disease.



360 ° Artery Analysis

Cleerly analyzes each of your heart arteries in 360 degrees to capture the important metrics.



Every Millimeter of Every Vessel

Cleerly evaluates each of your coronary arteries and their branches with sub-millimeter resolution.

Know Your Test: What Does the Cleerly Analysis See?

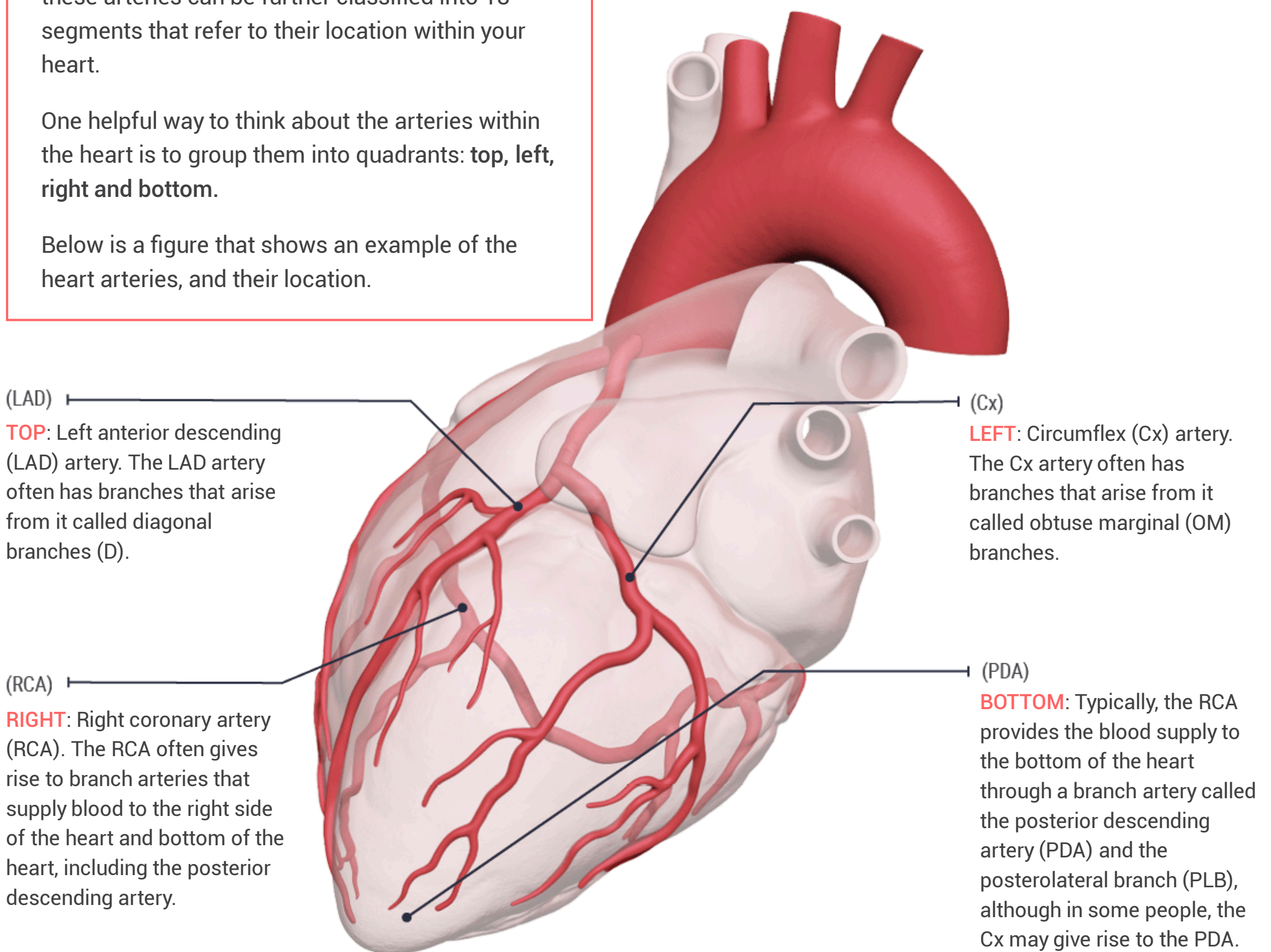
Let's get to know your heart

The first step in the Cleerly analysis is to identify and label each of your heart's arteries and branches. There are 3 major artery territories: Left Anterior Descending (LAD) artery, Circumflex (Cx) artery, and Right Coronary Artery (RCA). In general, there are approximately 7-10 arteries and branches that make up the 3 major artery territories. Together, these arteries can be further classified into 18 segments that refer to their location within your heart.

One helpful way to think about the arteries within the heart is to group them into quadrants: **top, left, right and bottom.**

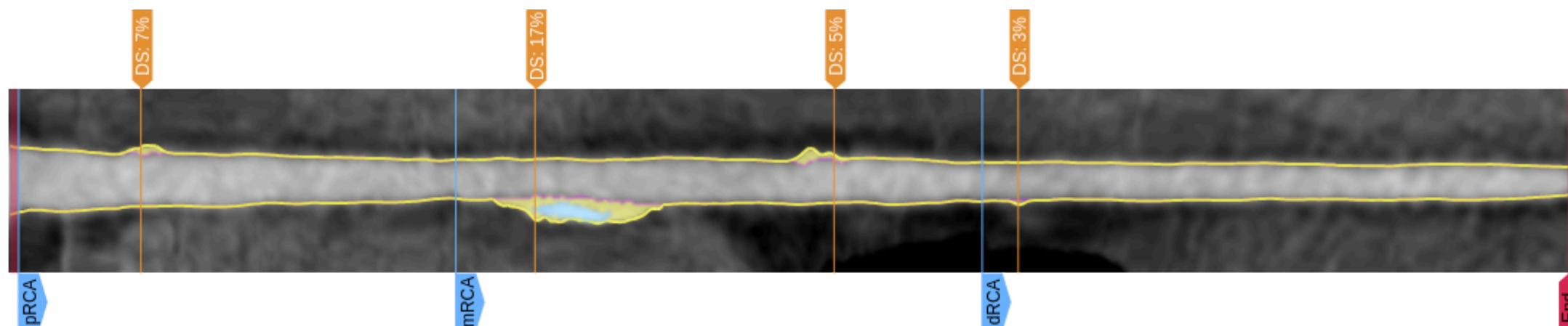
Below is a figure that shows an example of the heart arteries, and their location.

One additional point to know is that the LAD and Cx often arise from a shared artery called the left main (LM). Because the LM provides blood to both the LAD and Cx, it is a very important artery.



04 Know Your Heart: Detailed Clearly Analysis

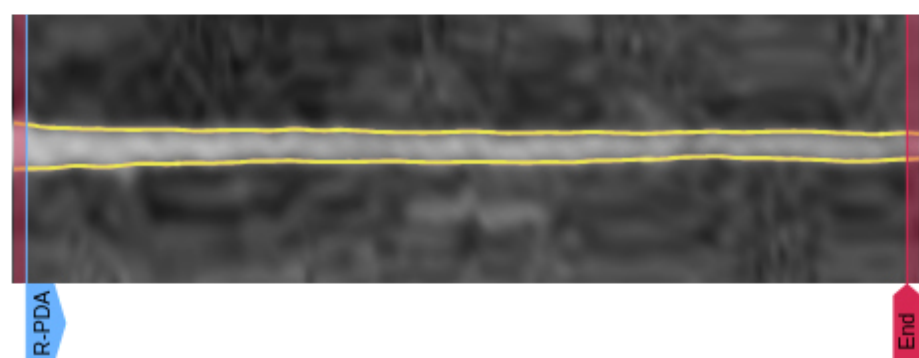
Right Coronary Artery (RCA)



89 mm³ 5.7% PAV Total Plaque Volume	0.1 mm³ < 0.1% PAV Low-Density - Non-Calcified Plaque Volume	77.3 mm³ 4.9% PAV Total Non-Calcified Plaque Volume	11.7 mm³ 0.7% PAV Total Calcified Plaque Volume
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17% Greatest Diameter Stenosis	1.1 Highest Remodeling Index
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Right Posterior Descending Artery (R-PDA)

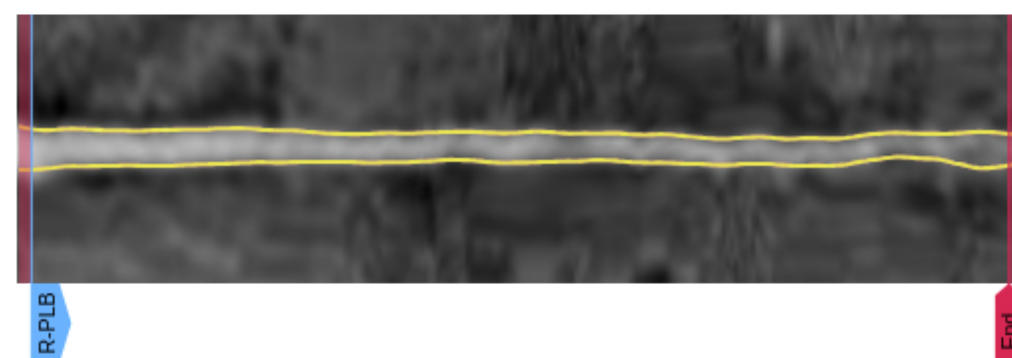


0 mm³ 0% PAV Total Plaque Volume	0 mm³ 0% PAV Low-Density - Non-Calcified Plaque Volume
0 mm³ 0% PAV Total Non-Calcified Plaque Volume	0 mm³ 0% PAV Total Calcified Plaque Volume

N/A Greatest Diameter Stenosis

1 Highest Remodeling Index

Right Posterior Lateral Branch (R-PLB)



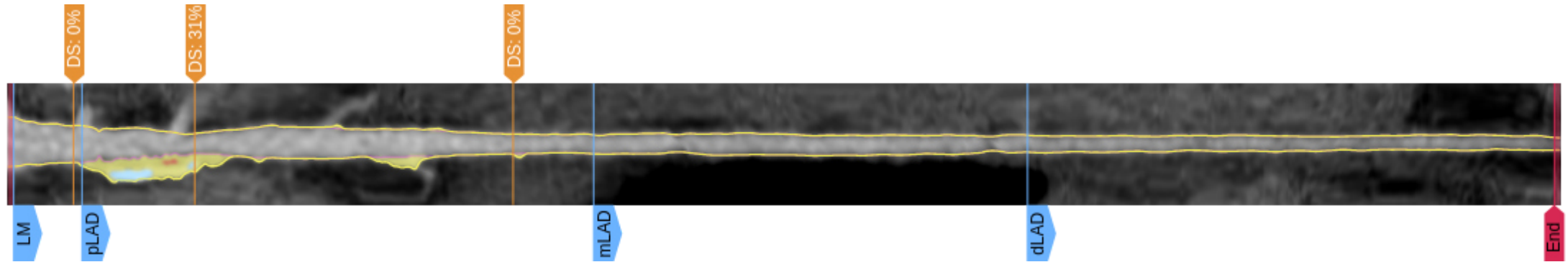
0 mm³ 0% PAV Total Plaque Volume	0 mm³ 0% PAV Low-Density - Non-Calcified Plaque Volume
0 mm³ 0% PAV Total Non-Calcified Plaque Volume	0 mm³ 0% PAV Total Calcified Plaque Volume

N/A Greatest Diameter Stenosis

1 Highest Remodeling Index

Know Your Heart: Detailed Clearly Analysis

Left Main and Left Anterior Descending (LM+LAD)

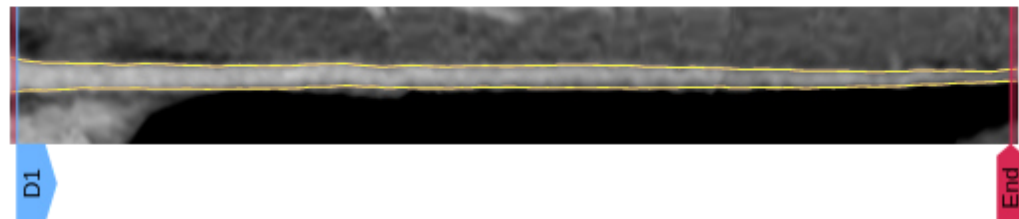


232.3 mm³ Total Plaque Volume	14.7% PAV	5.4 mm³ Low-Density - Non-Calcified Plaque Volume	0.3% PAV	216.1 mm³ Total Non-Calcified Plaque Volume	13.6% PAV	16.2 mm³ Total Calcified Plaque Volume	1% PAV
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31% Greatest Diameter Stenosis	1.3 Highest Remodeling Index
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① A lesion spans the LM and pLAD with 0% in LM and 31% in pLAD.

First Diagonal Branch (D1)

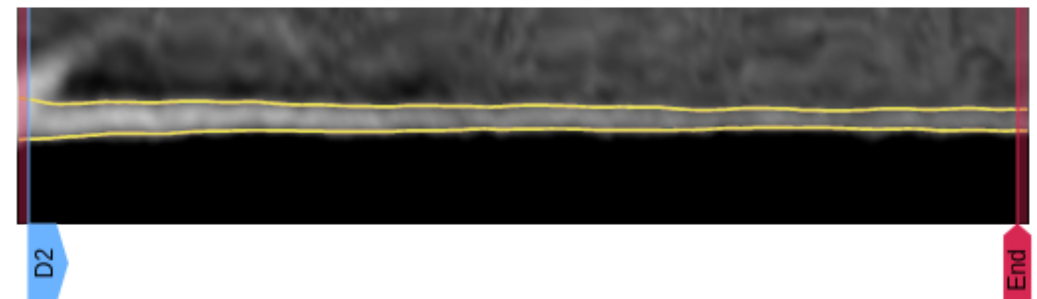


0 mm³ Total Plaque Volume	0% PAV	0 mm³ Low-Density - Non-Calcified Plaque Volume	0% PAV	0 mm³ Total Non-Calcified Plaque Volume	0% PAV	0 mm³ Total Calcified Plaque Volume	0% PAV
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N/A Greatest Diameter Stenosis

1 Highest Remodeling Index

Second Diagonal Branch (D2)



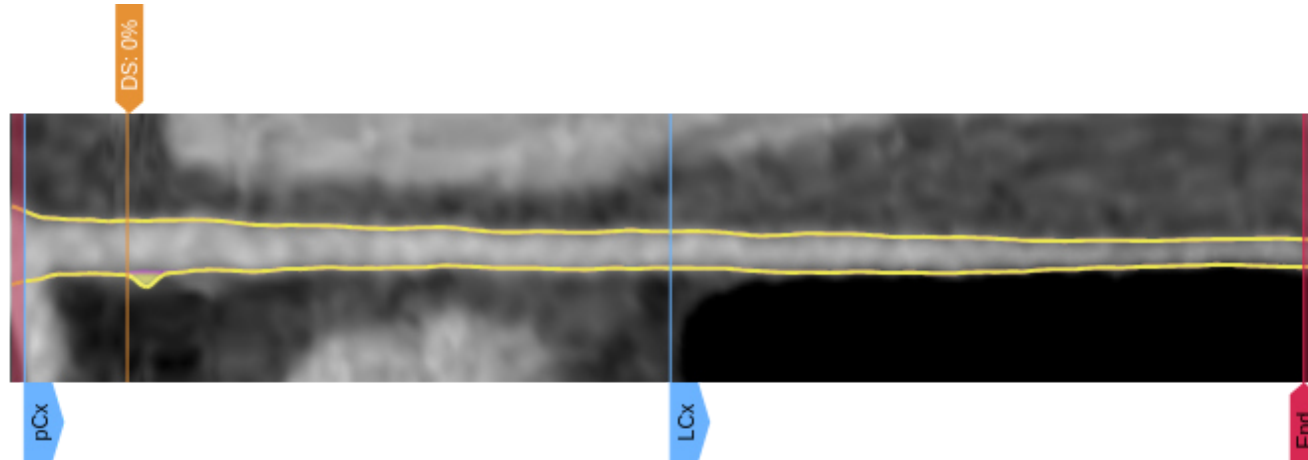
0 mm³ Total Plaque Volume	0% PAV	0 mm³ Low-Density - Non-Calcified Plaque Volume	0% PAV	0 mm³ Total Non-Calcified Plaque Volume	0% PAV	0 mm³ Total Calcified Plaque Volume	0% PAV
------------------------------------------------	---------------	----------------------------------------------------------------------	---------------	--------------------------------------------------------------	---------------	----------------------------------------------------------	---------------

N/A Greatest Diameter Stenosis

1 Highest Remodeling Index

Know Your Heart: Detailed Cleerly Analysis

Circumflex (Cx)



2 mm³ 0.6% PAV
Total Plaque Volume

0 mm³ 0% PAV
Low-Density - Non-Calcified Plaque Volume

2 mm³ 0.6% PAV
Total Non-Calcified Plaque Volume

0 mm³ 0% PAV
Total Calcified Plaque Volume

0% Greatest Diameter Stenosis

1.1 Highest Remodeling Index

First Obtuse Marginal (OM1)

Normal Variant

Second Obtuse Marginal (OM2)

Normal Variant

Know Your Heart: Detailed Cleerly Analysis

<p>Left Posterior Descending Artery (L-PDA)</p> <p>Normal Variant</p>	<p>Left Posterior Lateral Branch (L-PLB)</p> <p>Normal Variant</p>
<p>Ramus Intermedius (RI)</p> <p>Normal Variant</p>	

Glossary of Terms

Atherosclerosis:The process whereby plaque builds up in the walls of the heart arteries.

Blood Pressure:Pressure of the blood within the arteries. It is produced primarily by the contraction of the heart muscle.

Cholesterol:A fatty substance made by the body and found in some foods. Cholesterol is deposited in the arteries in coronary artery disease.

Coronary Arteries: Blood vessels that supply the heart muscle with oxygen-rich blood. There are three main coronary artery territories: Left Anterior Descending Artery (LAD), Left Circumflex Artery (LCx), and Right Coronary Artery (RCA). In general, there are approximately 7-10 arteries and branches that make up the 3 major artery territories.

Coronary Artery Disease (atherosclerosis): A build-up of plaque material in the coronary artery that causes narrowing of the artery. Coronary Computed Tomography Angiography ("Cat Scan"):A advanced non-invasive imaging test that looks at the arteries that supply blood to your heart.

Distal:Term used to label the end portion of the heart artery.

Heart Attack (myocardial infarction):Also known as myocardial infarction, a heart attack is caused by a lack of blood supply to the heart muscle that occurs from occlusion of the artery due to a combination of plaque and blood clot.

Hypertension:High blood pressure.

Invasive Angiogram:A invasive procedure performed using x-ray imaging to see the arteries of the heart.

Ischemia:Condition in which there is a combination of atherosclerosis and stenosis that may reduce the blood flow through the heart artery limiting oxygen-filled blood supply to the heart.

Occlusion:A blockage in the heart artery.

Plaque:Deposits of a combination of fats, inflammatory cells, proteins and/or calcium material along the lining of arteries seen in atherosclerosis (see above definition for atherosclerosis).

Arterial Remodeling:Vascular Remodeling refers to the direction in which plaque grows. When positive vascular remodeling (outward) occurs, the plaque grows outward in an attempt to make certain the inner portion of the blood vessel remains free of obstruction. When negative vascular remodeling (inward) occurs, the portion of the vessel where blood flow shrinks in size.

Proximal:Term used to label the beginning portion of the heart artery.

Risk Factor:Traits people have that are linked to the development of coronary artery disease. Some cannot be modified such as gender and advancing age. Some may be managed through healthy lifestyles, Other risk factors can be successfully managed through medical therapy, and include high cholesterol, diabetes, high blood pressure, and obesity.

Risk Marker:As opposed to risk factors – which increase an individual's predisposition for heart disease – risk markers are measures of actual disease.

Statin: Medication prescribed to lower blood cholesterol levels. Stenosis: Narrowing of the heart artery.

Stress Test:A test used to provide information about the adequacy of blood to the heart muscle during times of stress, such as at maximum exercise or through increased flow following administration of a medication.

Surrogate Measure:indirect measure that may correlate with heart disease, but may not pinpoint each and every individual with and without disease.

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About This Report

Cleerly uses information from your medical images to assist your physician in providing you with improved diagnosis and potential risk of heart disease. You should know that there are many other potential factors that may contribute to your overall heart health. These factors include such things as your genetics, other health conditions, level of physical activity, diet, tobacco use, psychosocial state and environmental factors. This report does not account for these other factors, and you should consult your physician for information on how these factors may influence your risk.

This report is not a substitute for information you receive from your physician or healthcare provider. It is very important for you to talk with your physician about these results, any questions that you have and possible actions that you may take to further lower your risk.

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