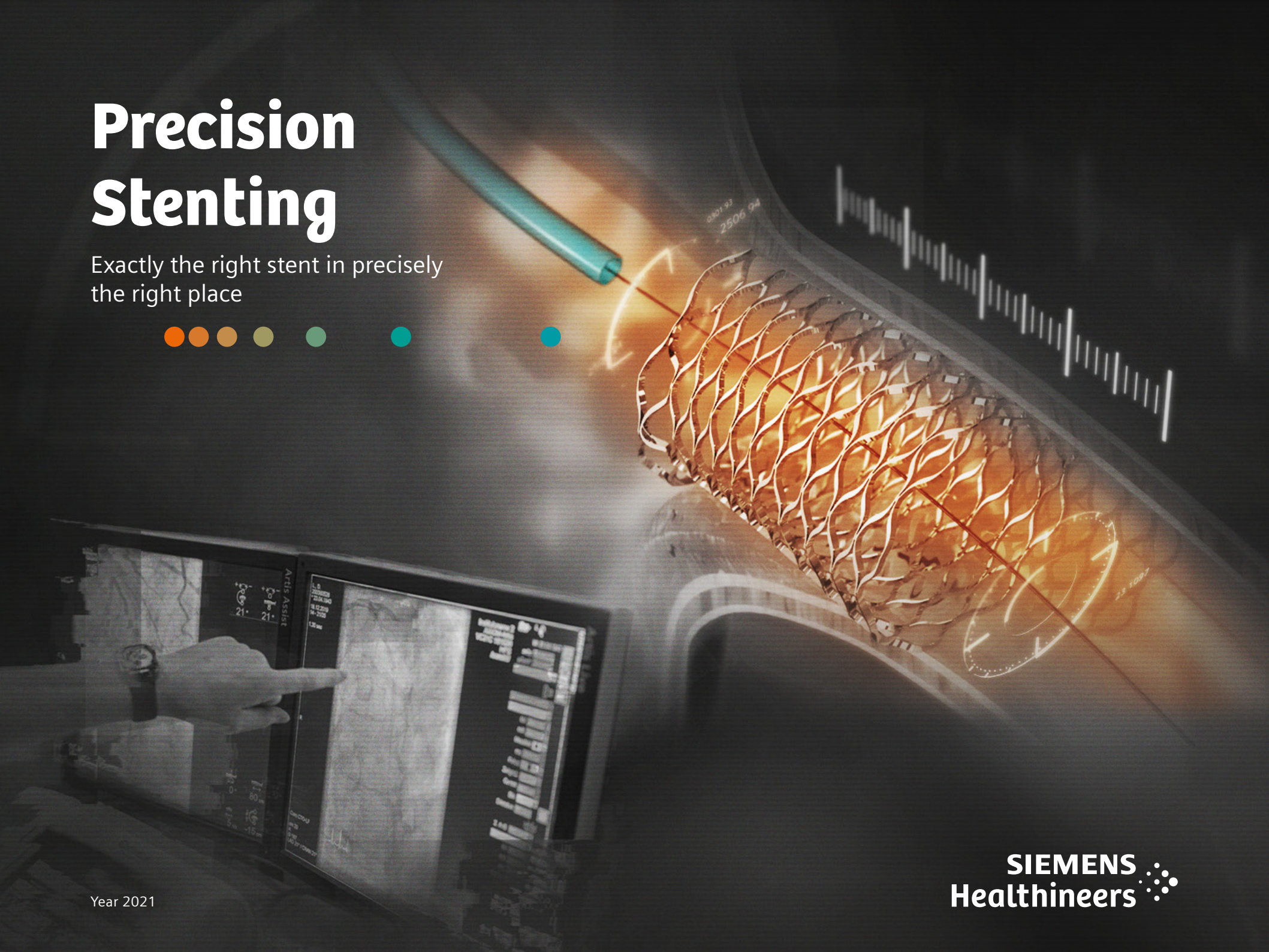
Precision Stenting

Exactly the right stent in precisely the right place



Year 2021

SIEMENS Healthineers

If you asked the average person about the importance of minimizing measurement errors and maximizing accuracy when performing a Percutaneous Coronary Intervention (PCI), the first thing they would probably do is ask what PCI is. Once this was explained, however, even non-medical people would undoubtedly declare that if you are inserting something into a patient's heart, precision at every step is critical.

The problem is that the challenge of improving precision in PCI is in many ways becoming harder to overcome, because more complex PCI procedures are increasingly more common, accounting for approximately 40 % of all PCI cases today.[1]

The solution to that problem may well lie in a robotic system that allows for accurate lesion measurement as well as precise stent placement. The system is called Corindus CorPath GRX, and it helps to reduce measurement errors, as well as the incidence of LGM and subsequently the need for extra stents.[2]

For cardiologists who have always had to rely on their eyes, their judgment, and their extraordinary skills, the promise of increased accuracy might well seem too good to be true. This paper takes that concern as a starting point and explores the various questions that understandably surround this new system:

1. **Why can't we fully rely on what we see?**
2. **What can this system do to improve stent placement?**
3. **Can this system deliver improved patient outcomes?**
4. **At the end of the day, is this system worth the investment?**

The answers to these questions paint a clear and convincing picture of a robotic system that is an absolute game-changer when it comes to precision stenting, and a win-win for both cardiologists and their patients.

How does Corindus CorPath GRX work?

Corindus CorPath GRX is a robotic system that helps to create a safe and healthy workspace for interventionalists. It allows operators to perform interventions by manipulating guidewires, guide catheters and devices from a radiation-shielded, ergonomic workplace with a set of joysticks and touchscreen controls without the need to wear heavy protective lead. Automated movements of the robotic system aid operators in navigating tortuous anatomies and crossing complex lesions. Exact measurement of anatomy aids in selecting the appropriate stent, while precise movements support accurate device-positioning. All this can contribute to more consistent, high-quality outcomes. These capabilities allow more operators to perform complex PCI with confidence and help interventionalists to reduce unwarranted variations.

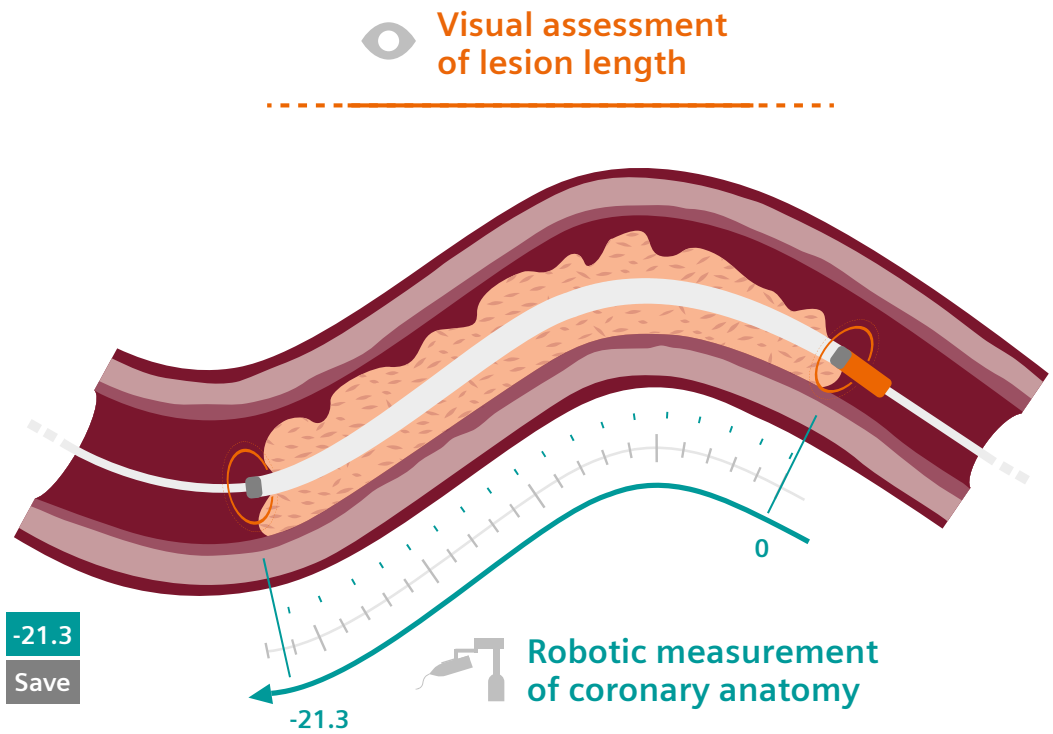
Chapter 1

Why can't we fully rely on what we see?

The simple answer is that sometimes our eyes get it wrong. That is true in the things we observe day to day; it is particularly true when we are trying to estimate the length of a lesion. Think about what cardiologists in the cath lab are dealing with. They are looking at a constantly moving 3-dimensional object – the heart – in only two dimensions, on a screen which is 6 feet (1.8 meters) away. And while doing that, they must assess the length of a tiny lesion, while taking into account foreshortening, angulation, and vessel overlap.

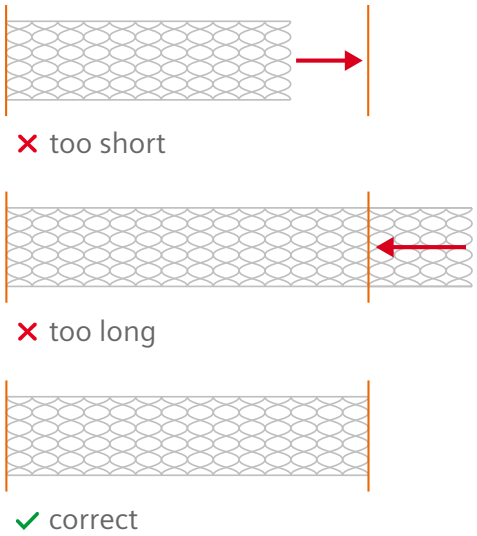
On top of that, as any cardiologist knows, visual assessment of lesion length can be particularly challenging in moderately (45-90°) and extremely (> 90°) angulated lesions. It is therefore no surprise that numerous studies have shown a high degree of inter- and intra-operator variability associated with visual assessment of stenosis, when compared to objective measurement techniques.[6-10]

The fact is that two times out of three, visually estimating lesions does not work as well as it should,[2] and the wrong stent length is selected. Whether too long or too short, neither is optimal in providing the best possible patient care. But the latter is particularly problematic as these cases require additional stents to cover the full lesion, which raises the prospect of overlapping stents – the consequences of which are not yet known. What is known, however, is that even a small amount of missed lesion coverage can increase the chances of restenosis and TVR.



2 of 3

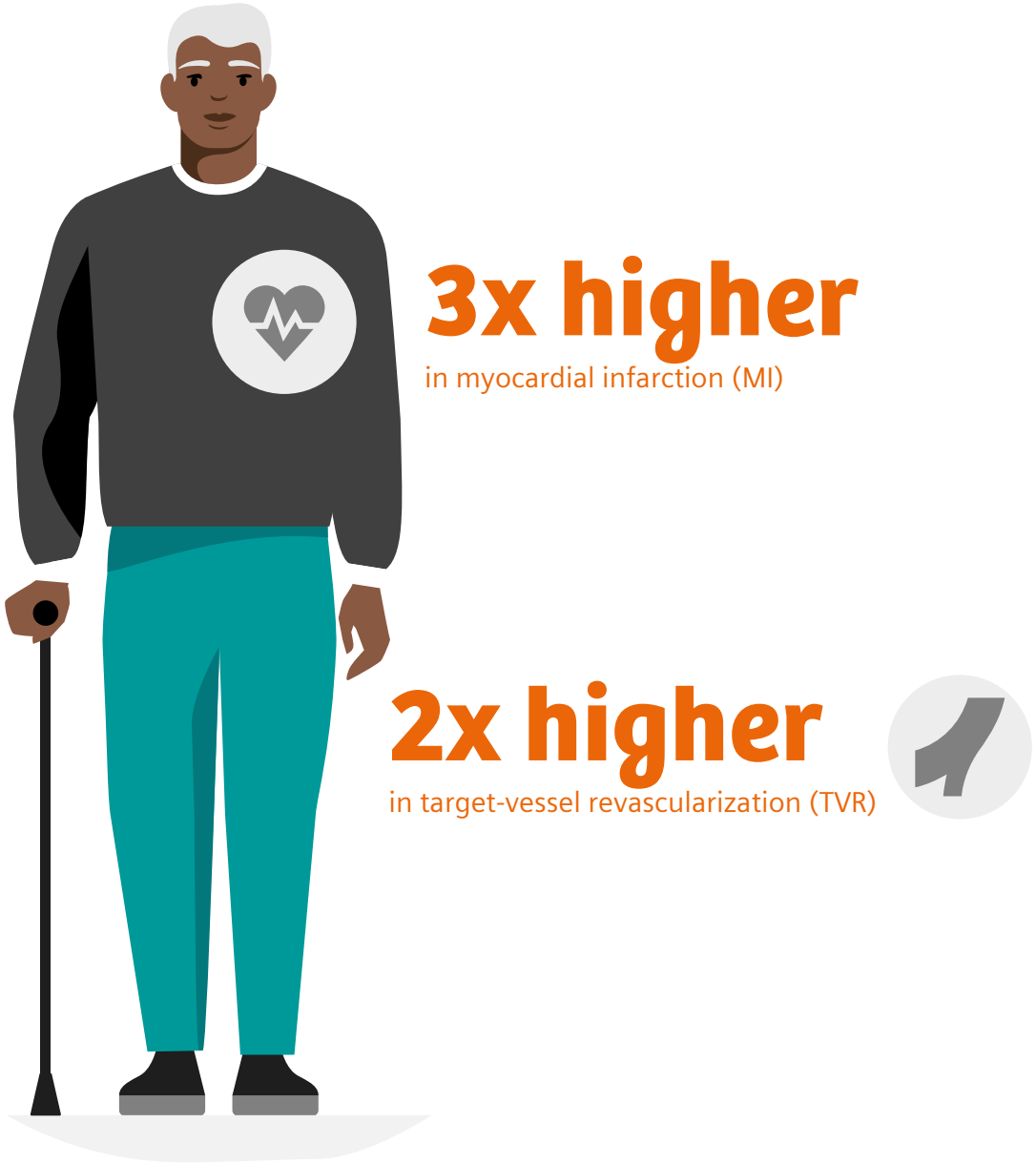
stents are selected inaccurately after visual assessment[2]



Inappropriate stent length selection is one of the reasons for geographic miss (GM). Geographic miss occurs in 66.5 % of PCI patients, with a high prevalence of longitudinal geographic miss (LGM), which occurs in nearly half (47.6 %) of all PCI patients. Suboptimal stenting from lack of precision can have serious impact on patient outcomes. GM is associated with a twofold increase in target-vessel revascularization (TVR) rates, and a threefold increase in myocardial infarction (MI) rates within one year.[3]

Inappropriate stent selection is a root cause of GM. More than two-thirds of visually estimated lesions result in inappropriate stent length selection.[2]

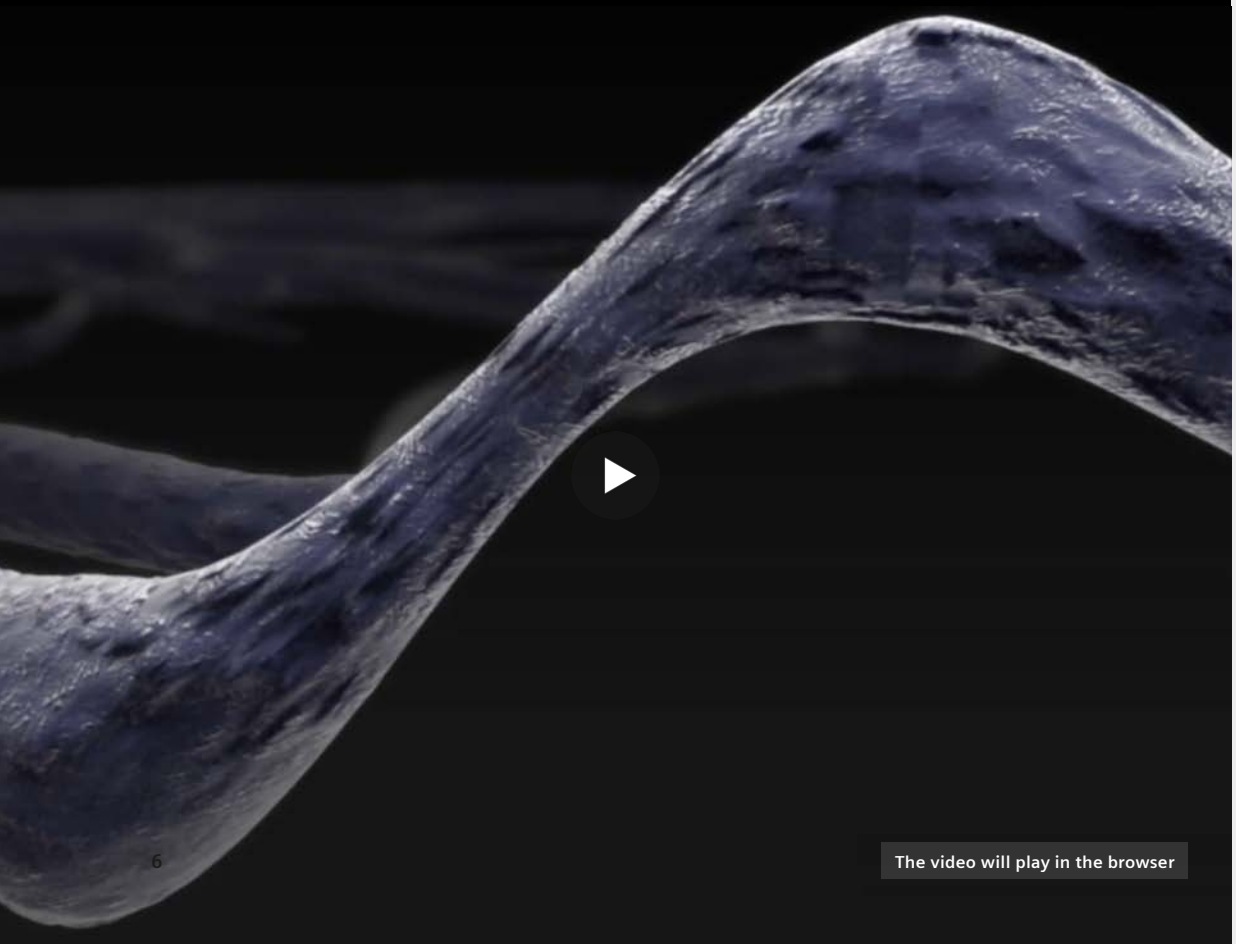
With robotic-assisted PCI, the ability to pull back the device at a steady, constant speed allows for the exact measurement of coronary anatomy down to a fraction of a millimeter.



Patient with GM

Watch how CorPath GRX allows sub-mm measurement even under difficult conditions.

Feature explained in 1 min



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Advance precision down to a fraction of a millimeter

CorPath GRX allows direct measurement of coronary anatomy with sub-mm accuracy – in less than 30 seconds. You can determine the precise lesion length, which allows you to select the appropriate stent length – virtually eliminating the need for extra stents. One comparison between visual assessments and robotic-assisted measurements has suggested that the use of robotic systems could lead to 8.3 % fewer stents being used.[1] The system also addresses inter- and intra-operator variability. No matter which operator, regardless of the time of day or day in the week, the system delivers much-needed accuracy. Measurement of lesion length using CorPath GRX can minimize measurement errors, lower the incidence of LGM, and reduce the need for extra stents.[1]

Chapter 2

What can this system do to improve stent placement in high-risk lesions?

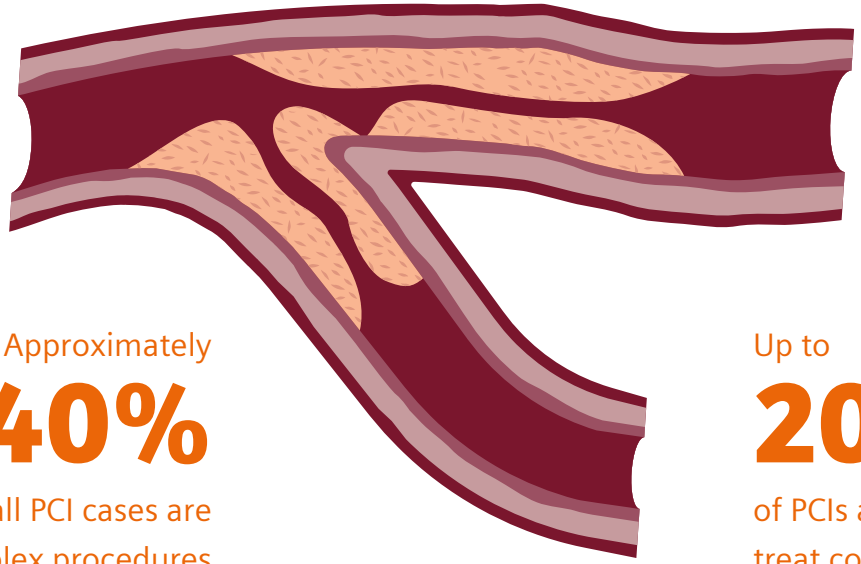
Accurate stent placement is particularly crucial to the success of treatment of complex, high-risk lesions. Today, this level of precision is more frequently required than ever before – as noted above, complex PCI procedures are increasingly common, today accounting for approximately 40 % of all PCI cases.[3]

One prominent example where precision matters is treatment using a two-stent strategy, where you want to make sure that there is no gap between the two stents on the one hand, and that the overlap of the stents is as short as possible on the other hand.

Up to 20 % of PCIs are performed to treat coronary bifurcations.[12] PCIs in these circumstances are renowned for being technically challenging and historically have been associated with lower procedural success rates and worse clinical outcomes than when used to treat non-bifurcation lesions.

Aorto-ostial lesions as well as bifurcation lesions still remain among the outstanding challenges of treatment with percutaneous coronary intervention. Bifurcation lesions are associated with increased rates of procedural complications, restenosis and adverse events than lesions in the body of the vessel. Abrupt side branch closure, side branch ostial restenosis and stent thrombosis are among the complications associated with the treatment of bifurcation lesions.

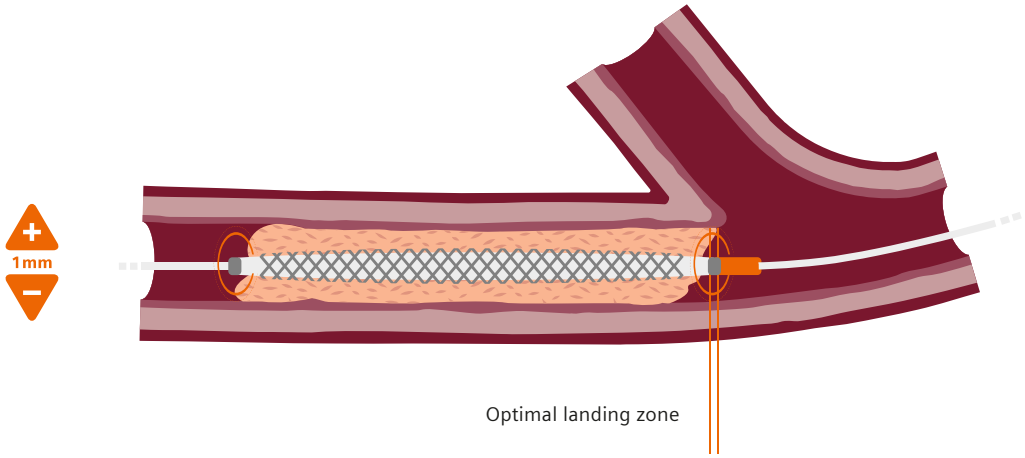
Poor predictability in terms of procedure duration and success, associated with high risk for complications, often results in healthcare providers assigning these cases to rare expert, high-volume interventionalists only – or even deferring these patients to other, more specialized institutions.



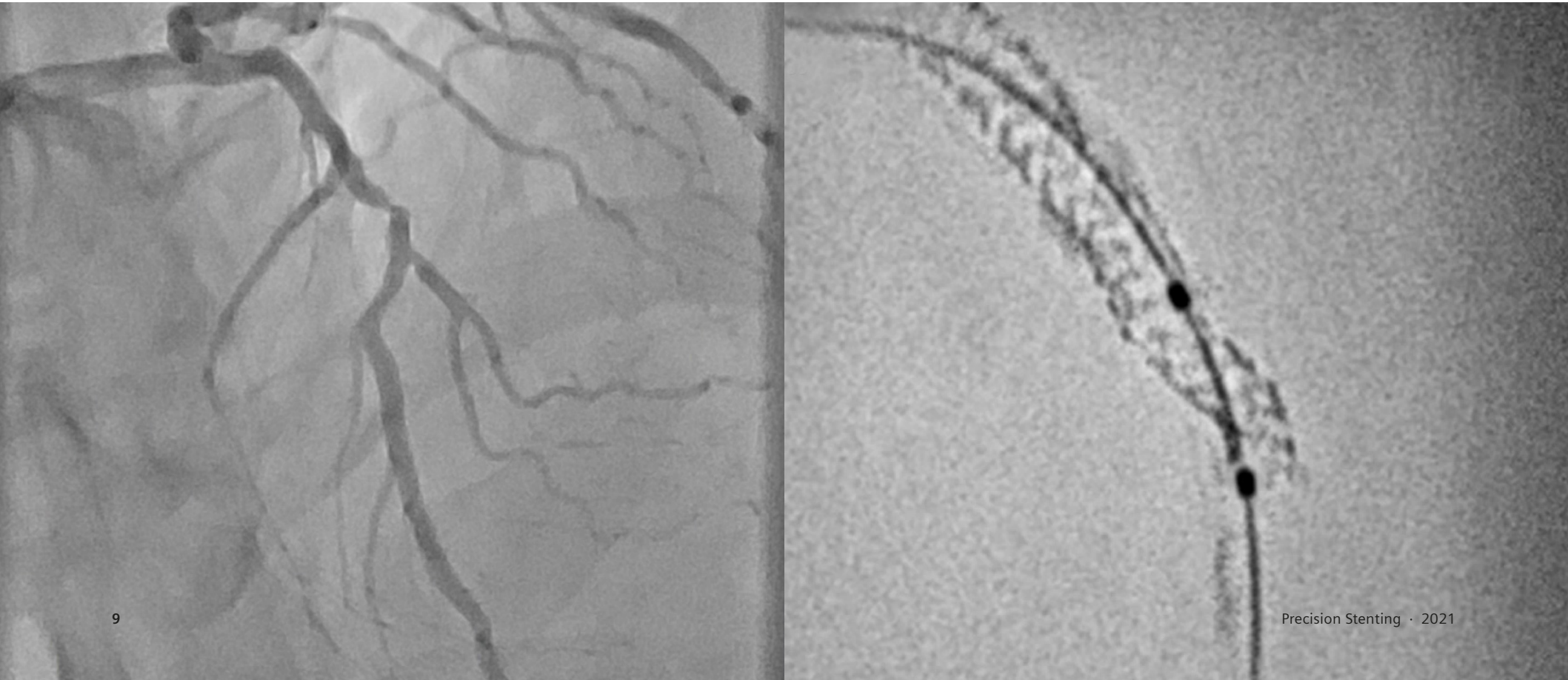
Approximately
40%
of all PCI cases are complex procedures

Up to
20%
of PCIs are performed to treat coronary bifurcations

CorPath GRX not only facilitates measurement of coronary anatomy to aid in the selection of appropriate stent length, but also allows cardiologists to treat complex lesions, such as ostial and bifurcation lesions, with 1mm device movements and active guide-catheter control. Given the significance of precise device placement, this robotic system is making a strong case for being the default option in complex PCI.

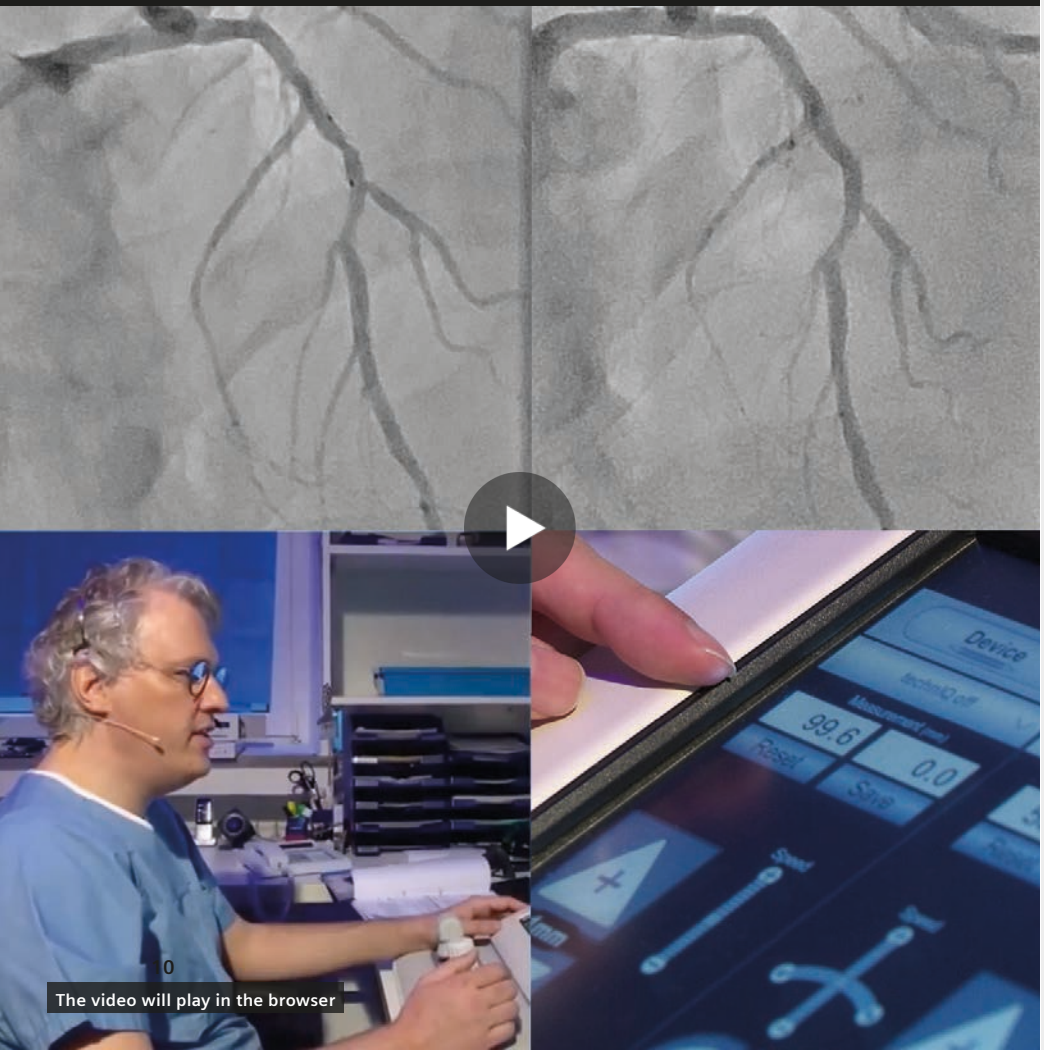


Robotic-assisted intervention of left anterior descending coronary artery disease
Image courtesy: St. Johannes Hospital Dortmund, Germany



What precision looks like

Recorded case: See Helge Moellmann, MD (St. Johannes Hospital Dortmund, Germany) perform a robotic-assisted PCI of a tight, calcified stenosis in the left anterior descending artery in close proximity to the diagonal branch. The robotic system supports him in crossing the lesion and positioning the 8mm stent precisely.



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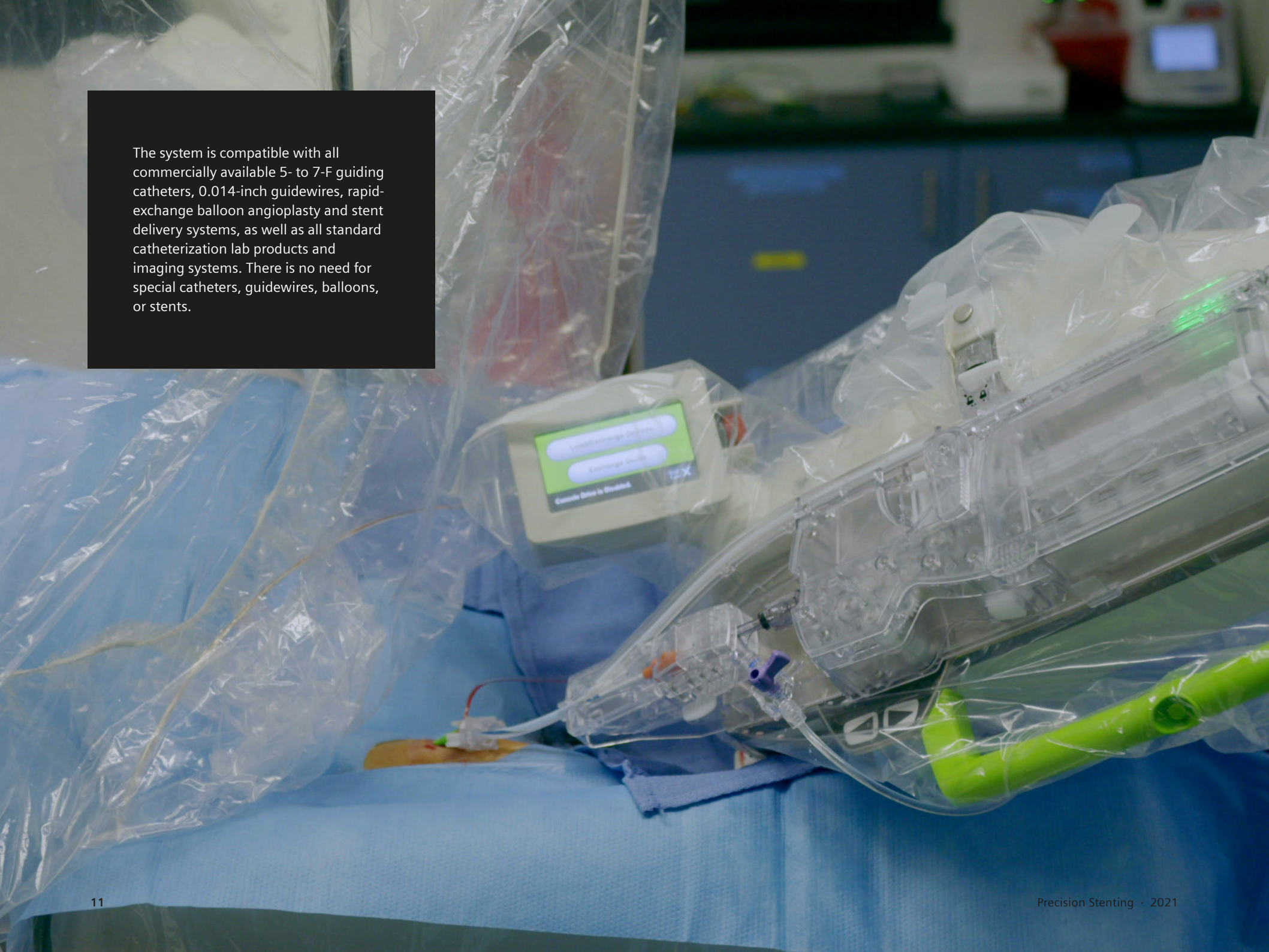
If you want precise stent placement, you want CorPath GRX

For some time now, leading interventionalists as well as patient organizations have emphasized the need for greater precision in conventional PCI practices and technologies, specifically with regard to stent placement. CorPath GRX is answering that call.



The system is compatible with all commercially available 5- to 7-F guiding catheters, 0.014-inch guidewires, rapid-exchange balloon angioplasty and stent delivery systems, as well as all standard catheterization lab products and imaging systems. There is no need for special catheters, guidewires, balloons, or stents.

Chapter 3

Can robotics really improve patient outcomes?

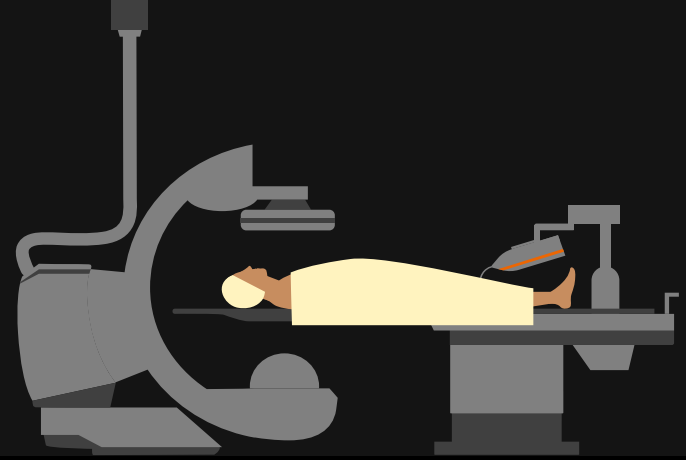
Our answer to this question is an emphatic yes. Robotics are no longer a "new thing" in medicine. There are already numerous examples of procedures where robots are used to augment the capabilities of their human operators. Some examples include:

- Urologic surgery with prostatectomies
- Orthopedic surgery with hipreplacements
- Neurosurgery with hematoma evacuations
- Plastic surgery with follicular implants for hair replacement

In these procedures, robots provide their operators with much-needed additional precision and reliability. They can do the same thing for cardiologists performing PCI.

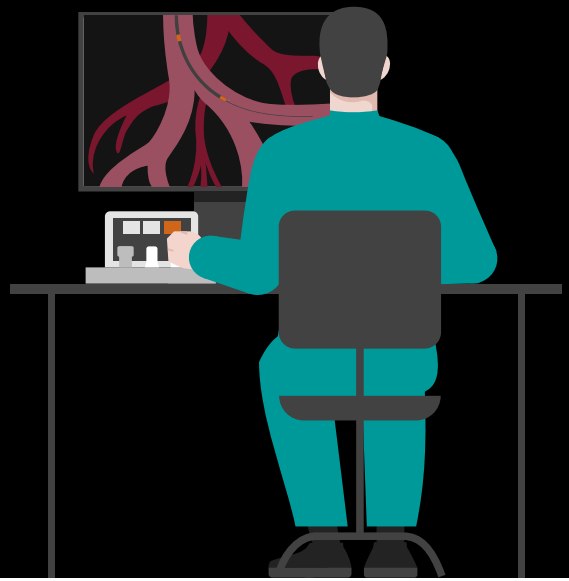
Is there data comparing the accuracy of conventional PCI vs. R-PCI?

Yes, there is. And what it shows is that as a result of its ability to accurately measure lesion length and place stents correctly, R-PCI has a significantly lower incidence of LGM compared to manual PCI: 12.2 % to 43.1 %, respectively ($P < 0.0001$).[5]



12% to 43%

R-PCI compared to manual PCI has a siginficantly lower incidence of LGM[5]



Exactly how does the system support and enable the precise treatment of high-risk lesions?

Beyond accurate measurement of coronary anatomy and device movements in discrete 1 mm steps there is one other critical aspect of the robotic system: It keeps guidewires, the device and the guide catheter rigidly in place. During the procedure, guidewire, device, and guide catheter are each individually controlled by the robotic drive of the system. This provides superior stabilization for the guide catheter, in addition to manipulating the wire and device. A locking mechanism differentiates between the wire and the device movements. This results in additional stability for the wire while advancing the interventional devices over it, avoiding telescopic slippage.

Active control of the guiding catheter, including adjustment and repositioning, can help facilitate treatment of high-risk lesions. A study of data from the post market registry of the system shows that active guide-catheter control was required in about 44 % of lesions treated.[11]

CorPath GRX builds on the skills of cardiologists to deliver even more accuracy - reliably

The consensus among cardiologists clearly seems to be that there is a time for physicians to make judgments and take matters into their own extremely capable hands, and there is a time to delegate pure arithmetic and absolute precision to computers. R-PCI allows you to do just that. It allows you to achieve consistent, reproducible, standardized, high-quality results, reducing variation and improving patient care. And it allows you to look at your patient and say: "Your lesion was measured accurately and fixed with exactly the right stent placed in exactly the right place. You have every reason to expect the best possible outcome."

"The precision provided by robotic assistance and the reduction in radiation exposure can be of fundamental importance."

Holger Nef, MD, Vice Chairman Cardiology,
University Hospital Giessen and Marburg, Germany

Chapter 4

At the end of the day, is this system worth the investment?

Yes. At the end of the day, this system is worth the investment, because it provides clear and significant return on investment (ROI). There are a number of ways of looking at this, and every one of them yields evidence of the value of R-PCI.

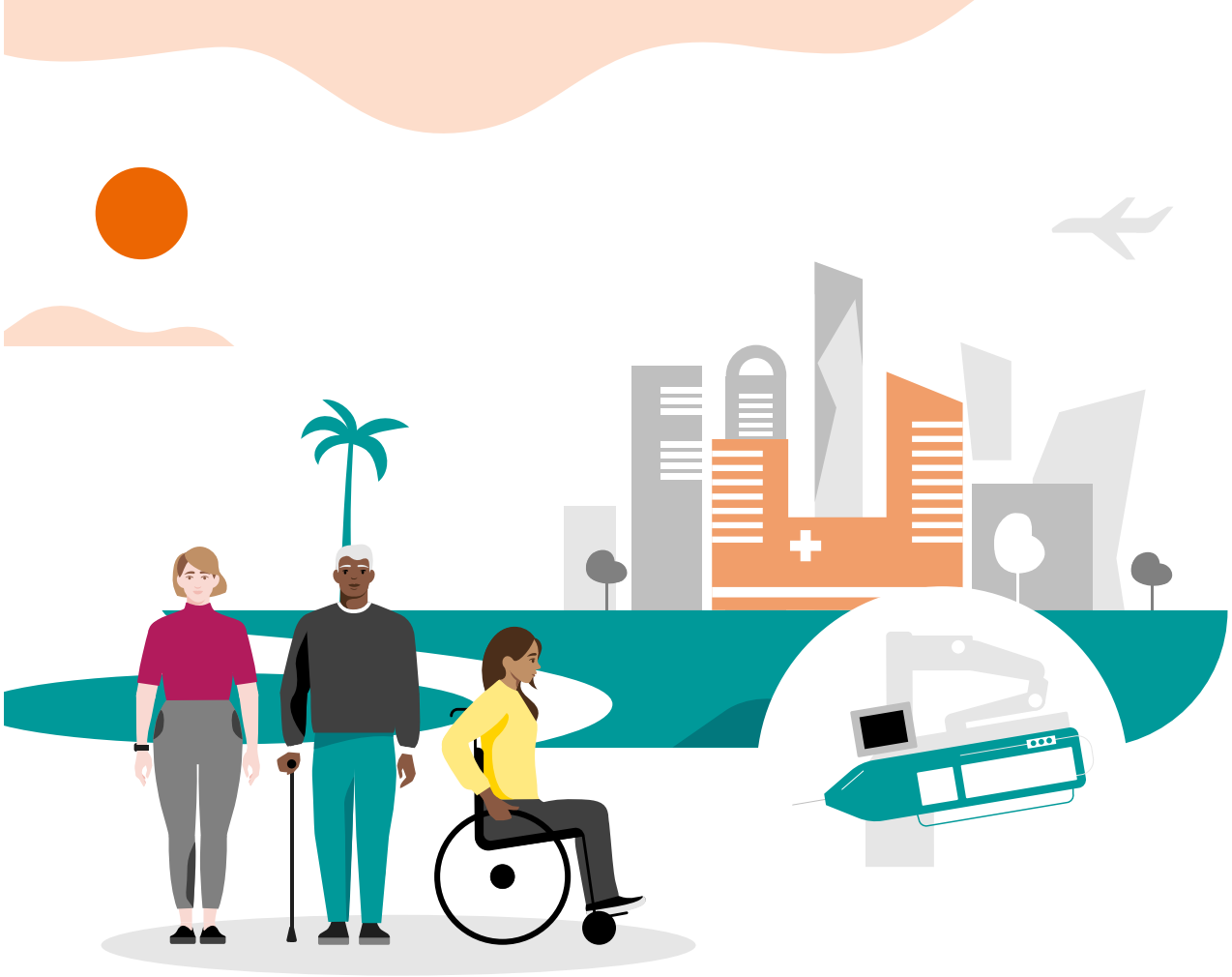
First, consider the value of needing fewer stents. As noted above, the robotic system provides the opportunity to reduce the number of unnecessary additional stents required to compensate for LGM and associated costs for stents and the time required to deliver these stents.

Second, consider the value of not having to deal with complications, TVR and MI, associated costs and their potential impact on the reputation of your institution.

Users report using the system for interventional treatment of bifurcation lesions, lesions that might still be treated by coronary artery bypass grafting (CABG) surgery. In these cases, the robotic system may help to provide cost savings to your institution by shifting cases from more costly surgery to an interventional procedure. This usually involves lower resource costs for delivery of treatment – cath lab vs. operating room – and results in shorter lengths of stay in the hospital.

Then consider the opportunities presented by this robotic system. Users report that they are now able to treat high-risk lesions with confidence – cases which they formerly deferred to more specialized institutions. The investment in CorPath GRX will help organizations realize their ambitions of more rewarding, complex cases.

Finally, consider the value of attracting more patients. Better results could lead to more patients. Improved long-term clinical outcomes for complex cases can help to raise your institution's reputation, leading to an extended catchment area with more referring physicians.



Patients seek

Increased accuracy

Shorter procedures

Better outcomes

Simply put, precision stenting pays off

CorPath GRX has the potential to pay off, in better patient outcomes, fewer complications, fewer unplanned readmissions and increased patient volume. It can bolster your growth ambitions by expanding your services into treatment of more challenging, complex cases. That is a return-on-investment worth exploring.

Looking to learn more? Ask to talk to an expert about the Corindus CorPath GRX Robotic System here.

Corindus CorPath GRX:
Advancing interventions with vascular robotics

Having highlighted the topic of **precision stenting** in this issue, the next paper will dig deeper into **automation of interventional procedures**. We'll be taking a closer look how the robotic system can provide interventionalists with advanced skills from high-volume operators. Standardization and greater predictability are among the beauties of automation and we will be discussing its value to guidewire navigation in tortuous anatomy and in crossing long, calcified lesions. Finally, we'll be discussing the potential of this technology to allow for successful treatment of more high-risk, complex cases.

PHYSICIAN PROTECTION

Reduce time in lead and radiation exposure

PROCEDURAL AUTOMATION

Navigate complex anatomies routinely

PRECISION STENTING

Position the right stent in the right place

DIFFERENTIATING TECHNOLOGY

Elevate your lab for patients and staff

Want to learn more?
To schedule a chat with a Corindus CorPath GRX robotic system expert here:

Book your personal virtual demo now ↗

Yes, I want to get in contact with a Siemens Healthineers sales representative. ↗

Yes, please add me to the newsletter list. ↗

For more information on Corindus CorPath GRX please visit:
siemens-healthineers.com/roboticpci

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The CorPath GRX System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters, and remote manipulation of guide catheters during percutaneous coronary and vascular procedures.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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