



## **RADIFOCUS™ GUIDE WIRE M:**

RESEARCH ON THE POTENTIAL  
CLINICAL, WORKFLOW AND COST  
BENEFITS ACROSS EUROPE

We have conducted a survey of European clinicians to explore how the attributes of their RADIFOCUS™ Guide Wire M translate to clinical benefits, procedure efficiency and potential cost saving.  
Read on to find out how the RADIFOCUS™ Guide Wire M could benefit you.

**TERUMO**  
INTERVENTIONAL  
SYSTEMS



Increasing healthcare demand means focusing your spend to ensure you get optimum value across all your cost centres, including medical devices. Guidewires are common devices used in coronary and peripheral endovascular procedures ranging from diagnostic angiography to angioplasty and stenting, with each clinical situation demanding a guidewire matched to the task and the operator. Our research suggests that by selecting the right guidewire and guidewire suppliers, you can enhance patient throughput and operation efficiency, reduce consumption of guidewires, and potentially minimise procurement complexity<sup>1</sup>.

## Guidewires – a key tool in endovascular interventional procedures

Guidewires are important access tools used in a wide range of endovascular procedures, including angiography, catheterisation, embolisation, angioplasty and stenting (Figure 1). Guidewires, as the name suggests, are designed to direct endovascular devices like catheters or stents into their desired anatomical location in the vascular system<sup>2</sup>. That means they need to move easily through blood vessels without damaging them and yet must also be able to penetrate or cross lesions or blockages within vessels<sup>2,3</sup>.

Guidewires have been in use for over 40 years and their design has evolved to address different clinical presentations and techniques<sup>3</sup>. The essential attributes of guidewires are size, stiffness, coating and tip configuration<sup>2</sup>. A vast array of guidewires combining various attributes has emerged as endovascular interventions and technology have expanded<sup>2</sup>.

Guidewires are used diagnostically and therapeutically as part of peripheral vascular procedures and in interventional cardiology procedures<sup>2</sup>.

In 2021 in Europe, the estimated number of procedures is:

- 696 000 for endovascular peripheral vascular procedures<sup>4</sup>
- 2 220 000 for interventional cardiology procedures<sup>5</sup>.

The CAGR for endovascular procedures is between 1 and 3% (2019–2030)<sup>4,5</sup>.

Figure 1. Guidewires: a quick overview

### Why are they used?

Guidewires are designed to navigate, cross lesions and position interventional devices inside blood vessels.

### What endovascular procedures are they used in?

- **Angiography:** an imaging technique to visualise blood vessels
- **Angioplasty:** a procedure used to improve blood flow in a diseased or narrowed artery or vein
- **Catherisation:** the introduction of a hollow tube into a vessel to deliver medicines or devices or to withdraw material
- **Embolisation:** a procedure used to reduce or block blood flow in a vessel, e.g. to stop abnormal bleeding
- **Stenting:** insertion of a stent to open a blocked vessel and improve blood flow

### Who uses them?

- Angiologists
- Interventional cardiologists
- Interventional radiologists
- Vascular surgeons

### What are they?

Guidewires are access devices comprising a<sup>1,2</sup>:

**CORE:** this runs the length of the wire and determines the stiffness, flexibility and shape of the wire, its kink resistance and how easy it is to steer.

**TIP:** the end of the wire that is inserted into the vessel. The core in the tip is usually tapered to make it flexible at the end. The taper, shape, softness and durability of the tip are all important to its function.

**COATING:** this alters the friction against the vessel wall. Hydrophilic coatings improve the ease of movement of guidewires, making them preferable when navigating tortuous vessel systems or crossing tight lesions<sup>6</sup>. The smooth navigation provided by hydrophilic coatings is referred to as lubricity.

Overall performance of a guidewire is affected by its construction, tip design and coating<sup>1</sup>. Having the right guidewire for the right job in the hands of interventional specialists is essential to clinical success and smooth efficient workflow.





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## Terumo and RADIFOCUS™ Guide Wire M

Terumo is an established leader in the guidewire market with their unique, lubricious, hydrophilic RADIFOCUS™ Guide Wire M. In the 35 years since its launch, the RADIFOCUS™ Guide Wire M has become the preferred tool of many interventional specialists thanks to its specific attributes and the wide range of guidewire options suitable for different procedures (Table 1)<sup>4</sup>.

## Terumo – contributing to society through healthcare<sup>7</sup>

Terumo was founded over 100 years ago in Japan as a high-quality thermometer manufacturer. In the last century, Terumo has grown into a global company offering diverse medical devices and services. Terumo's extensive business portfolio ranges from vascular intervention and cardio-surgical solutions, blood transfusion and cell therapy technology, to medical products essential for daily clinical practice, such as transfusion systems, diabetes care and peritoneal dialysis treatments.

## History of the RADIFOCUS™ Guide Wire M

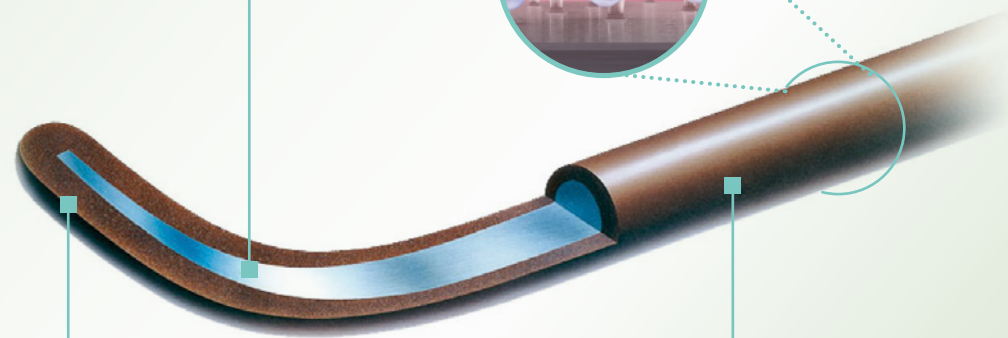
The Radifocus™ Guide Wire M was introduced already 35 years ago.

The RADIFOCUS Guide Wire M is a wire made of super-elastic Nickel-Titanium alloy (Nitinol).

Nitinol is a metal alloy that is extremely flexible.

The outer layer of RADIFOCUS™ Guide Wire M consists of Terumo's exclusive hydrophilic polymer coating M Coat™

When activated, this coating provides superior lubricity and durability<sup>8,9</sup>.



The RADIFOCUS™ Guide Wire M has a rounded tip with a flexible tapered design.

This minimises damage to the vessels as the guidewire is advanced<sup>8</sup>.

The core wire of RADIFOCUS™ Guide Wire M is entirely coated with a polyurethane layer containing tungsten (inner layer). It ensures non-traumatic insertion of the wire and also makes it radiopaque so it shows up on imaging<sup>8</sup>.

## RADIFOCUS™ Guide Wire M characteristics

The RADIFOCUS™ Guide Wire M comes with various tip configurations and stiffnesses (Table 1), as well as different lengths, diameters and tip (distal flexible) lengths. This provides a comprehensive range of specialised wires to address most clinical situations.

**Table 1. The RADIFOCUS™ Guide Wire M range is designed to support a vast array of procedures**

TIP	CORE		
	Standard	Half Stiff	Stiff
Straight	✓		✓
Angled	✓		✓
J-tip The small atraumatic J-tip avoids the selection of side branches and minimises the risk of procedural complications <sup>10</sup>	✓	✓	
	Intended to direct a catheter to the desired anatomical location in the vascular system during diagnostic or interventional procedures.		
	The stiff shaft is designed for tight, stenotic, tortuous and narrow vessels		

The RADIFOCUS™ Guide Wire M is one of the leading choices for interventionalists<sup>4,5</sup>. Terumo funded a research project to explore why and to understand the benefits of the RADIFOCUS™ Guide Wire M for clinical practice and the broader procurement environment<sup>1</sup>.

## RADIFOCUS™ Guide Wire M survey of interventional specialists<sup>1</sup>

An online survey of 252 European interventional specialists was conducted in February 2021. The interventional specialists were selected based on their level of experience, their role and the clinical setting in which they work. This reflects the typical real-world use of guidewires and ensures the capture of expert input from experienced clinicians.

### Purpose of the survey

The survey explored the attributes of the RADIFOCUS™ Guide Wire M that clinicians find most beneficial and how these benefits translate into potential workflow enhancements, improved success rates, reduced failure rates and cost savings for procurement.

The results are presented in 4 parts:

1. The clinical features of the RADIFOCUS™ Guide Wire M recognised by clinicians
2. The associated benefits that are of greatest importance to interventional specialists
3. The relevance of these to procedural success and efficiency
4. How this potentially translates into economic benefits for centres.

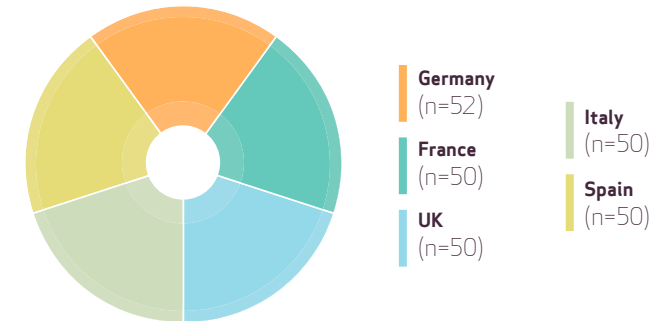
### About the clinicians surveyed

A representative, balanced sample of interventional specialists was obtained from 5 European countries: Germany, France, Italy, Spain and the UK. On average, each respondent had approximately 16 years' experience, with most working in academic teaching hospitals (Figure 2).

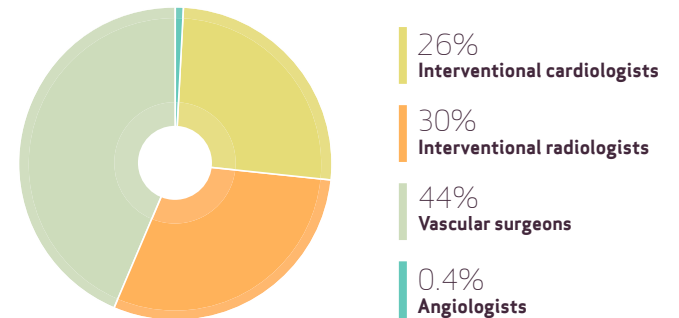
On average, the respondents performed approximately 129 interventional procedures per month using a range of devices, such as diagnostic and guiding catheters and sheaths. Hydrophilic guidewires were used in over 60% of those procedures. Interventional cardiologists reported lower hydrophilic guidewire usage than interventional radiologists or vascular surgeons. In interventional cardiology, non-hydrophilic coated wires are widely used, however, hydrophilic guidewires are considered a safer option for radial access to allow the navigation of complex vessel anatomy and to reduce the risk of spasm<sup>11</sup>.

Figure 2. Characteristics of the clinical sample group<sup>1</sup>

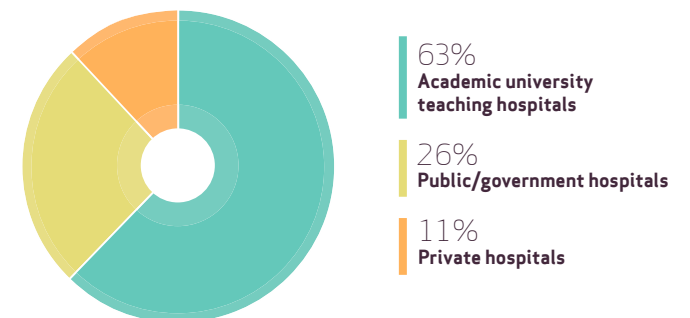
#### Country



#### Speciality



#### Type of hospital



## The key features of the RADIFOCUS™ Guide Wire M recognised by interventional specialists<sup>1</sup>

The respondents were shown statements summarising the key features of the RADIFOCUS™ Guide Wire M and asked to rate their level of agreement with them. Agreement was measured using a 5-point Likert scale where 1 = strongly disagree and 5 = strongly agree.

The majority of respondents showed high levels of agreement (rating 4-5) with all the described features of the RADIFOCUS™ Guide Wire M<sup>1</sup>:

77%

The RADIFOCUS™ Guide Wire's hydrophilic polymer coating (M Coat™) shows a superior lubricity

75%

Has a rounded tip of Nitinol core combined with a flexible tapered design

72%

Provides you with a comprehensive range of specialised guidewires

72%

Has a durable shape memory of the tip

70%

Shows a balanced transition from the tapered distal core to the more rigid proximal shaft

60%

Has the most flexible distal tip

Interventional specialists both recognise the key features of the RADIFOCUS™ Guide Wire M and associate them with specific benefits that aid interventional success and operational efficiency. Operator capability is obviously the primary determinant of procedure outcomes, however, as 1 German respondent observed:

**'Appropriate wires increase the likelihood of a successful intervention.'**

## The benefits of the RADIFOCUS™ Guide Wire M that are important to interventional specialists<sup>1</sup>

The respondents were asked to consider specific benefits of the RADIFOCUS™ Guide Wire M by rating the importance of the benefit on a 7-point scale where 1 = not important at all and 7 = extremely important.

The top three most important benefits (rated 6–7) by >70% of respondents are summarised and explained in [Table 2](#). These benefits are consistent with published literature on the desired performance characteristics of guidewires.

Other guidewires possess similar features to the RADIFOCUS™ Guide Wire M, however, almost half of respondents perceived **high trackability** and **good crossability** as more unique to the RADIFOCUS™ Guide Wire M than to other guidewires (rating 6–7 on a scale where 1 = not unique at all and 7 = extremely unique).

Table 2. Top benefits of the RADIFOCUS™ Guide Wire M explained<sup>1</sup>

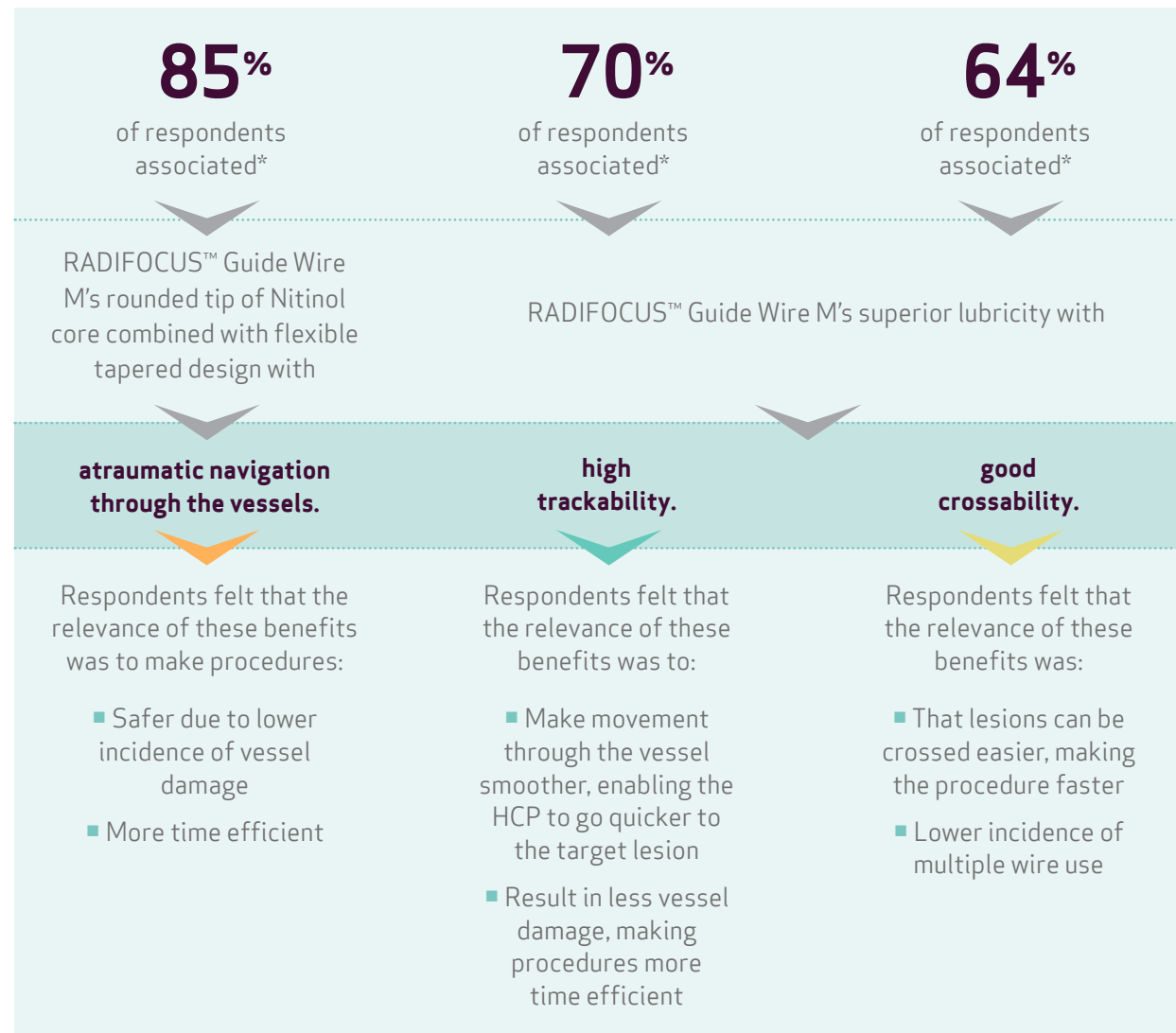
Benefit	Definition	Supporting information
<b>Atraumatic navigation through the vessels</b>	The ability not to harm the vessel when advancing.	Inadvertent injury is a risk with any endovascular intervention, so being able to minimise the risk of vessel perforation and flow-limiting dissection is very important <sup>12,13</sup> .  Clinical studies of the RADIFOCUS™ Guide Wire M report that complications or safety issues are rare <sup>6,9</sup> .
<b>High trackability</b>	The ability to advance through a vessel.	Vascular anatomy can be complex, with tortuous vessels and multiple branches. Guidewires need to be able to navigate these tortuous pathways and not get kinked or stuck in the vessel <sup>11,2,14</sup> .  High trackability of the RADIFOCUS™ Guide Wire M has been demonstrated in both plastic bench models of disease <sup>14</sup> and clinically in patients <sup>6,9</sup> . More recent bench tests have confirmed the high trackability of the RADIFOCUS™ Guide Wire M against a range of other hydrophilic guidewires <sup>14</sup> . Furthermore, the high trackability has been confirmed in post-marketing evaluations.
<b>Good crossability</b>	The ability to cross a lesion with little resistance.	Many interventional procedures using guidewires need access beyond a lesion or stenosis <sup>15</sup> . In fact, the treatment of a lesion is only possible when the guidewire is passed beyond the target lesion <sup>15</sup> . Having a guidewire that can do this, do it quickly and with minimal force is vital to procedural speed, safety and success.  Good crossability has been confirmed in clinical trials of the RADIFOCUS™ Guide Wire M <sup>9</sup> . Bench tests in model systems have shown that the RADIFOCUS™ Guide Wire M could cross lesions in around 10 seconds, while other hydrophilic wires were still not across after 5 minutes <sup>14</sup> . The good crossability of the RADIFOCUS™ Guide Wire M has been confirmed in post-marketing evaluations and bench tests against other hydrophilic guidewires <sup>8</sup> .



## Respondents believe that atraumatic navigation through the vessels, high trackability and good crossability are highly relevant to their procedural success and efficiency<sup>1</sup>

The respondents clearly linked the benefits of atraumatic navigation through the vessels, high trackability and good crossability to the characteristics of the RADIFOCUS™ Guide Wire M. More importantly, specialists identify that these are relevant to safety, procedural efficiency and wire use (Figure 3).

Figure 3. How RADIFOCUS™ Guide Wire M can aid procedural safety and efficiency<sup>1</sup>



\* Respondents were asked to agree with the association using a 5-point scale where 1 = strongly disagree and 5 = strongly agree. The percentage shows proportion of respondents selecting ratings 4 and 5.

## Potential economic benefits associated with RADIFOCUS™ Guide Wire M<sup>1</sup>

The survey asked interventional specialists to suggest the potential economic benefits of using hydrophilic guidewires in terms of savings in time, physician effort, cost and reduced failure rates.

### Savings in time and physician effort

Savings in time and physician effort were most frequently linked to good performance, specifically, the ability to complete procedures more rapidly and improve workflow or throughput of patients. With pressures building on waiting lists due to rising patient numbers, this may provide an opportunity to increase system capacity.

*'Efficient time management leads to better daily patient turnover and smaller waiting lists.'* **UK clinician**

*'Reduction in the duration of the procedure and better use of the time in the operation room (more operations in the same session).'* **Italian clinician**

### Cost savings

Approximately a third of respondents felt that cost savings primarily resulted from the use of fewer wires for each intervention. Although multiple guidewires may be employed for specific types of lesions, generally interventional specialists try to minimise the number of wires used, only changing wire if it should kink or fail to cross a lesion. A durable wire can therefore reduce consumable costs.

*'This saves a lot of money because we reduce the number of guidewires used during a procedure with a flexible and proper hydrophilic guidewire.'*

**French clinician**

*'The deterioration of the distal tip of a certain guidewire (non Terumo guidewire) or their kinking pushes us to use several of them resulting in increasing costs.'*

**French clinician**

### Savings from reduced failure rates

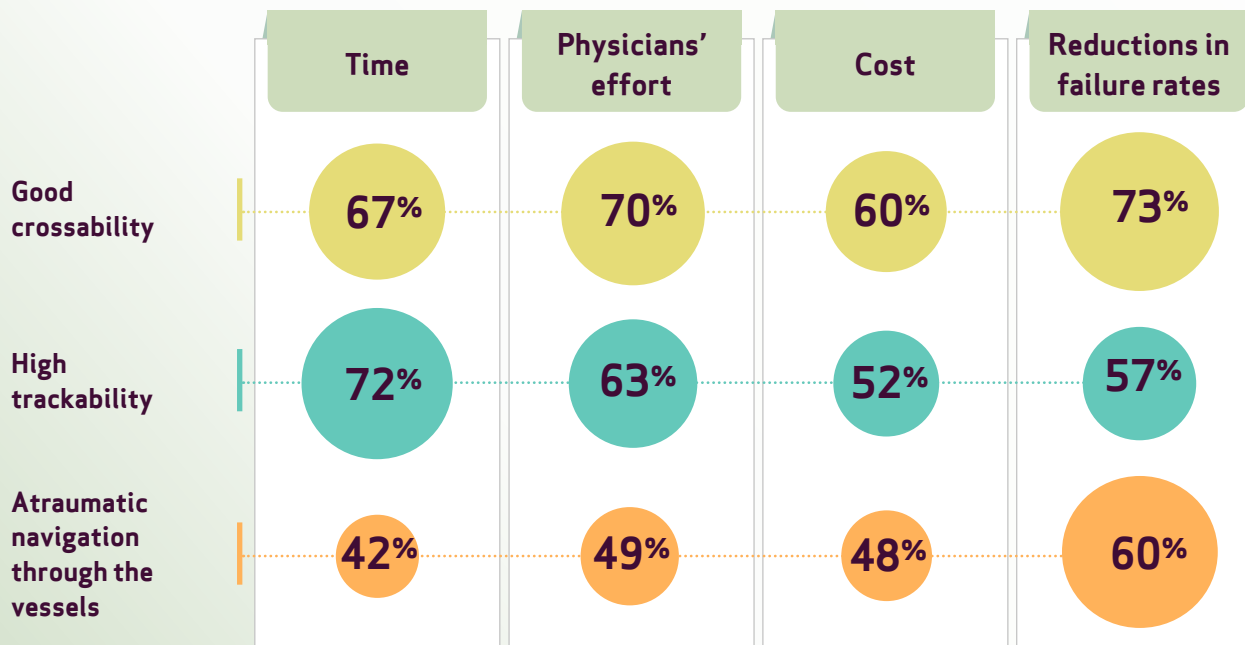
The majority of respondents stated that savings from reduced failure rates resulted from the good performance and high procedural success rates of hydrophilic guidewires. Furthermore, about 1 in 5 respondents cited the use of fewer wires as a key saving. Getting things right first time is an essential principle of clinical practice, so tools that make that more likely are clearly welcomed.

*'By using a hydrophilic guidewire on complex, calcified lesions/tortuous vessels it is possible to avoid waste of several guidewires and above all complications related to vessel damage. Also enables shorter interventions and exposure to lower ionizing radiation.'*

**Italian clinician**

*'Higher procedural success rates will mean fewer returns for alternative or secondary procedures.'* **UK clinician**

Table 3. The top three benefits\* with the highest potential for savings in time, physician effort, cost and reduced failure rates<sup>1</sup>



\*Percentage of respondents scoring the benefit in the top three benefits

Respondents believed that good crossability and high trackability have the highest potential to generate savings in physicians' effort, cost and time, while good crossability and atraumatic navigation were thought to have the highest potential to generate savings related to reduced failure rates. The top three benefits are shown in [Table 3](#).

It is worth remembering that the RADIFOCUS™ Guide Wire M is used in multiple types of procedures. For example, in 1 clinical study, the RADIFOCUS™ Guide Wire M was used in 17 different types of intervention<sup>6</sup>.

The comprehensive range of the RADIFOCUS™ Guide Wire M therefore gives clinicians access to a variety of guidewires, all with the optimum attributes needed to perform most endovascular interventions safely, efficiently and cost effectively.

## So what does this all mean for guidewire procurement?

Guidewires, in many ways, are a standard piece of equipment, often overlooked as a simple commodity product in a procurement exercise, yet this survey shows that clinicians believe their procedural success and efficiency can be enhanced if they have access to wires with the specific attributes found in the RADIFOCUS™ Guide Wire M. They also believe this translates to real economic benefits relevant to procurement (Table 4).

**Table 4. How use of the RADIFOCUS™ Guide Wire M benefits procurement<sup>1</sup>**

<b>Increased operational productivity</b>	<b>Reduced consumables spend</b>	<b>Fewer revisions, additional interventions or adverse events</b>
<p>Use of the RADIFOCUS™ Guide Wire M may enhance operator efficiency and patient throughput, meaning theatre time and personnel can be freed up.</p> <p>With lower failure rates, the time taken for alternative or secondary procedures may also be reduced.</p>	<p>Use of the RADIFOCUS™ Guide Wire M may result in less wire use per intervention, meaning you can generate cost savings in consumables.</p> <p>With lower failure rates, the reduced need for additional wires or other devices may minimise spend on additional consumables.</p>	<p>Use of the RADIFOCUS™ Guide Wire M may result in lower failure rates and a higher likelihood of a successful outcome first time.</p> <p>This may reduce complications and the costs associated with those.</p>
<p>Use of the RADIFOCUS™ Guide Wire M could help address the ever-growing waiting lists for endovascular interventions and reduce the pressure on clinical staff and systems.</p>	<p>Use of the RADIFOCUS™ Guide Wire M could help you optimise your consumables budgets for endovascular interventions across many clinical departments.</p>	<p>Use of the RADIFOCUS™ Guide Wire M may, therefore, potentially enhance patient experience and outcomes.</p>



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## Conclusions

The key benefits of the RADIFOCUS™ Guide Wire M are the ability to navigate delicate and complex vessels without damaging them (atraumatic navigation), the ability to stay on the right track through even the most tortuous vasculature (high trackability) and the ability to cross lesions and blockages within vessels (good crossability) to ensure interventional devices are positioned correctly and safely. These benefits result from the key attributes of the RADIFOCUS™ Guide Wire M's superior lubricity and its rounded tip of Nitinol core combined with flexible tapered design. In addition, the comprehensive range of the RADIFOCUS™ Guide Wire M ensures that clinicians have the optimum tool for most endovascular procedures.

It's hard to specifically quantify actual cost benefits from using the RADIFOCUS™ Guide Wire M given the vast array of interventions and clinical presentations where it is used. However, the survey clearly shows that there could be economic benefits related to procedural speed and workflow, clinician

effort, cost and reductions in failure rate. Specifically, the enhanced workflow potentially resulting from RADIFOCUS™ Guide Wire M use could translate into increased operational productivity – a valuable asset as waiting list pressures grow. Reductions in consumable spend from lower guidewire use are also possible – this may benefit cost centres across many different clinical departments. Finally, the potential of the RADIFOCUS™ Guide Wire M to reduce failure rates has clear economic benefits in terms of productivity and consumable use, with less need for secondary or additional procedures and devices. Most importantly, this also translates into positive patient experiences and outcomes.

The comprehensive range of RADIFOCUS™ Guide Wire M devices available ensures that clinicians have the right device with the optimum attributes at hand to help them perform a wide range of endovascular interventions safely, efficiently and cost effectively.

**Terumo can help you optimise the value in your spend on guidewires. To find out more, contact your local Terumo representative.**

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## Glossary

**Aneurysm:** a bulge in a blood vessel caused by a weakness in the vessel wall.

**Angiography:** an imaging technique used to visualise blood vessels.

**Angioplasty:** a procedure used to improve blood flow in a diseased or narrowed artery or vein.

**Catherisation:** the act of inserting a small hollow tube into the arteries or veins in order to either introduce material or a device into the body or to withdraw material.

**Crossability:** the ability of the wire to cross over a lesion.

**Embolisation:** a procedure used to reduce or block blood flow in a vessel. It is used to stop abnormal bleeding, close blood vessels supplying a tumour, remove abnormal vascular connections between arteries and veins, or to treat aneurysms.

**Lesion:** a wound or sore related to damage of the body. In terms of vascular disease, this relates to damage to the inside of blood vessels.

**Lubricity:** the ability of smooth wire operation by navigating through the vessels (including small vessels and tortuous anatomies).

**Occlusion:** a blockage that closes a blood vessel, preventing blood flow.

**Stenosis:** the pathological narrowing of a vessel.

**Stenting:** a procedure where an internal scaffold (stent) is inserted into an occluded or stenotic blood vessel to keep it open and re-establish blood flow.

**Trackability:** the ability of the wire to advance through the vessel.

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