

Press
Release
13 September 2022

HECHINGEN, Ger-
many and
CAESAREA,
Israel

BENTLEY ACQUIRED THE GOBACK CATHETER

“The acquisition of the GoBack catheter marks the start of inorganic growth for Bentley” said Sebastian Büchert, Bentley’s CEO. “We launched our first of six existing product families to the market in 2012 and have experienced significant growth since then. Now, only 10 years later, we are able to acquire this very innovative product. This strategic move further completes our product offering to hospitals and physicians to the benefit of our joint patients.”

The GoBack catheter is the only product capable of both crossing and re-entry, which simplifies the treatment of chronic total occlusion (CTO). The device is equipped with a curved nitinol needle that can be manipulated into straight or curved positions using the device handle. The catheter makes use of a 0.014” or 0.018” guidewire and can be used in below- and above the knee procedure thanks to its 2.9F and 4F profile respectively. “Bentley acquiring the GoBack makes me feel proud because. I am sure that with Bentley’s global footprint more physicians will have access to the catheter,” said Dan Rottenberg, CEO of Upstream Peripheral Technologies. “Our vision is to save limbs and reduce the number of amputations. With Bentley’s strong network more patients will have access to such treatment.”

The GoBack catheter is CE marked and FDA cleared. The application for the certification under the new European medical device regulation (MDR) has already been filed. The fact that the catheter also has a FDA clearance will give Bentley the opportunity to explore the US market much quicker as initially planned. Launched in 2019, the device is now available in 23 countries. It is the intention of Bentley to extend the global availability to all of the 80 markets in which Bentley is already active.

Bentley, a global leader in minimally invasive medical devices for vascular treatments, has acquired the rights of the GoBack catheter from Upstream Peripheral Technologies (Caesarea, Israel). This acquisition expands the company’s product portfolio, which is dedicated to improve the clinical outcomes of endovascular treatments.

Martijn Nugteren, Director Sales & Marketing, Bentley, says, “we will be really busy in the months ahead. Not only because we want to make the product commercially available in additional markets, but also due to the fact that we are going to rebrand the GoBack to BeBack. This is to make sure that our new product will be recognised as another leading product underneath Bentley’s brand umbrella. It is expected that the BeBack will officially be launched beginning of 2023, whereas the GoBack will stay available until then.”

Currently produced in Israel and initially shipped from there, a production transfer to the Bentley production facility in Hechingen, Germany, will be completed by 2025.

For further information, check: www.bentley.global

About Bentley

Bentley was founded in 2009 by medical entrepreneurs Lars Sunnanväder and Miko Obradovic. The company has seen substantial growth since the launch of its first product in 2012, and today operates a global distribution network in more than 80 countries. The seven top-line products in Bentley’s portfolio are:

- BeGraft coronary (2012)
- BeGraft peripheral: first generation (2013); second generation (2015)
- BeSmooth peripheral (2014)
- BeGraft aortic (2016)
- BeGraft PLUS (2017)
- BeYond (2020)
- GoBack/BeBack (2022)

About Upstream Peripheral Technologies

Upstream Peripheral Technologies is a privately held company, produces the GoBack Catheter to treat chronic total occlusions in angioplasty procedures. The company’s mission is to ensure that no patient is left untreated, and has helped physicians save thousands of patients from unnecessary leg amputations.

Contact:

Bentley InnoMed GmbH
Lotzenäcker 3
72379 Hechingen, Germany

THE BENTLEY STORY SO FAR...

2009 ● Bentley was founded

2012 ● BeGraft
coronary

2013 ● BeGraft
peripheral 1st generation

2014 ● BeSmooth
peripheral

2015 ● BeGraft
peripheral 2nd generation

2016 ● BeGraft
aortic

2017 ● BeGraft⁺
peripheral

2018 ● BeGrow First-in-Man

2019 ● EndoStore
by Bentley

2020 ● BeYond
venous

2022 ● BeBack
crossing catheter

...to be continued



YOU’LL BeBack

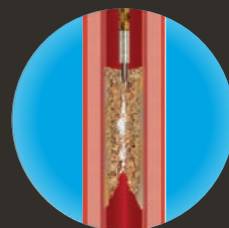


Bentley acquired GoBack®

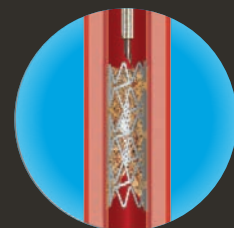
BeBack

crossing catheter

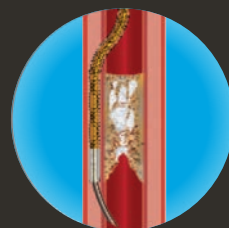
Steering through Chronic Total Occlusions (CTO) is often the most challenging part when treating heavily calcified lesions. The BeBack crossing catheter is the only device that provides an effective solution for CTO and limb salvage treatment, combining a maneuverable crossing catheter with targeted re-enty capability, in one single device. Intra-luminal as well as sub-intimal treatment of (re)stenotic lesions is possible from multiple approaches (antegrade, retrograde and cross-over). This makes the BeBack crossing catheter an effective solution for above and below the knee interventions.



CTO crossing



In-stent-Restenosis



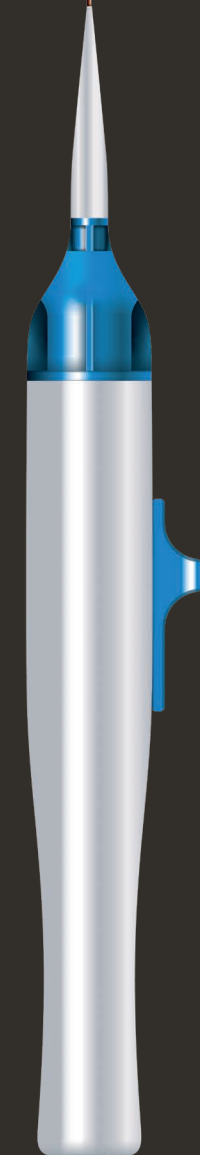
Subintimal crossing & re-entry

Product ordering information outside US

BeBack crossing catheter	2.9F,	80cm:	GB 603 014P 80L
BeBack crossing catheter	2.9F,	120cm:	GB 603 014P 120L
BeBack crossing catheter	4.0F,	80cm:	GB 600 018P 80L
BeBack crossing catheter	4.0F,	120cm:	GB 600 018P 120L

Product ordering information for the US

BeBack crossing catheter	2.9F,	80cm:	GB 603-US014P80L
BeBack crossing catheter	2.9F,	120cm:	GB 603-US014P120L
BeBack crossing catheter	4.0F,	80cm:	GB 600-US018P80L
BeBack crossing catheter	4.0F,	120cm:	GB 600-US018P120L



Product specifications

Multiple applications - support, crossing and re-entry catheter: all in one single product

2.9F and 4F - Effective above and below the knee solution in two sizes

360° rotational Nitinol needle, full steerable control and targeted re-entry capability

BeBack
crossing catheter

#405068 Rev.1

“Based on our experience, the GoBack speeds up procedures and improves the success-rate”



DR. ANDREJ SCHMIDT
LEIPZIG, GERMANY

Bentley asked two endovascular specialists for their opinion on the GoBack catheter and its value in treating (complex) Chronic Total Occlusions (CTOs). Here, Dr. Andrej Schmidt, senior interventionalist at the University-Clinic Leipzig, Germany who has experience of the GoBack in over 200 cases; and Dr. Michael Lichtenberg, Chief Medical Officer of the Angiology Department at Vascular Centre Clinic Arnsberg, Germany, share their experience with the device.

What are the greatest challenges when treating CTOs?

AS: One of the greatest challenges of CTOs is to accomplish guidewire-passage, a part of the procedure that can be extremely time-consuming, consecutively requiring high radiation- and contrast-dosages. Failure to pass the guidewire from antegrade in femoropopliteal CTOs is as high as 20% and can be even higher in very complex lesions. A device that speeds up these complex interventions and improves the success-rate of guidewire passage is welcomed.

ML: CTOs can be challenging for a number of reasons including localisation, lesion length, and calcification. Without dedicated crossing or re-entry catheters, crossing a CTO can be both time consuming, frustrating and sometimes leads to having to abort the procedure. As such, a dedicated crossing and support catheter is of great value in challenging CTO cases.

Can you briefly describe the GoBack catheter and its role in the treatment of CTO's?

AS: Based on our experience, the GoBack speeds up procedures and improves the success-rate. The device consists of an inner pushable and retractable small needle held within a low-profile, robust catheter. The needle can be extended to different lengths and when

straight and minimally extended, it can be used for penetrating fibrotic, hard, calcified plaque-material, while at full extension, it curves and can be used to penetrate from a subintimal space back into the true lumen, similar to a reentry-device. A radiopaque C-marker at the proximal catheter tip assists directing of the needle. Its stability and low profile makes it easy to handle and access the lesion.

ML: The GoBack catheter offers a two-in-one support in challenging CTO cases. With a low profile (4F or 2.9F) the GoBack acts as a support and crossing catheter guiding a 0.018” or 0.014” guidewire through a CTO into the true lumen. With subintimal CTO crossing now as a standard recanalisation technique, the GoBack also features a re-entry needle biopsy into the true lumen from subintimal space. These two unique aspects make it much simpler for the interventionalist to cross a CTO lesion.

What are the benefits of the GoBack compared to traditional treatment options?

AS: Historically, there have been several devices used to cross a CTO. The main benefit of the GoBack is its ability to be successfully used in multiple approaches such as crossing through CTOs but also to re-enter from the subintimal space back into the true lumen.

Because of its low profile, it can be used in very tight lesions, e.g. severely calcified CTOs or small diameter infrapopliteal arteries. In addition, it can be easily introduced through a retrograde approach, even via the tibial arteries. Despite the GoBack being smaller than many other devices for CTO-crossing, which run over a 0.014” guidewire, the GoBack can be used over an 0.018” guidewire which is of great benefit with difficult CTOs that require stable guidewires.

THE EXPERTS OPINION ON THE GOBACK CATHETER



DR. MICHAEL LICHTENBERG
ARNSBERG, GERMANY

“GoBack makes it easy to guide the catheter and wire in all directions through a CTO”

ML: GoBack makes it easy to guide the catheter and wire in all directions through a CTO. The C-marker, as mentioned earlier, helps to steer the re-entry needle towards the true lumen. For retrograde puncture (transpedal or transtibial), the 2.9F low profile catheter tracks very well even in calcified tibial vessel.

Some last words on the GoBack?

AS: When the GoBack-catheter was introduced to our cathlab, we immediately had the impression, that this device was different. The high success-rate and the large variety of situations where the device can be applied for is very impressive.

AS case study with GoBack

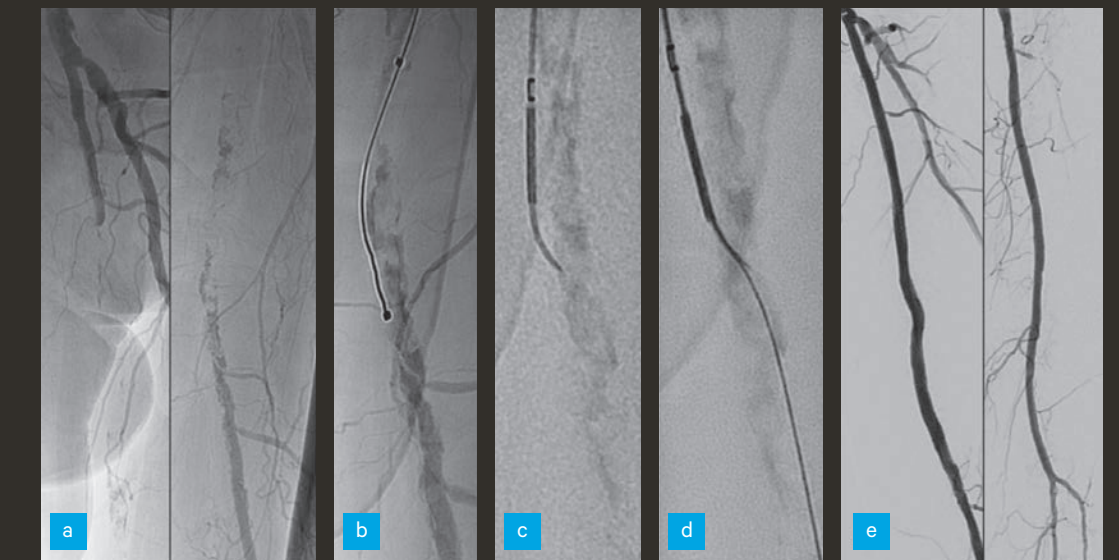


Figure 1. GoBack as a reentry-device in a severely calcified CTO of the left superficial femoral artery in a patient with severe claudication (figure 1a). The guidewire passed the CTO subintimally, and re-entering of the distal patent lumen was not possible (figure 1b). Insertion of the GoBack catheter and redirection of the guidewire into the distal patent lumen (figure 1c and d). Result after stenting (figure 1e).