**Title: LINC 22: PRIZER Study With Dr Deloose: Renzan™ Stent in Pts With PAD**

**Participants: Dr Koen Deloose**

**Date: 08/06/2022**

**Dr Koen Deloose**

- I'm Dr. Koen Deloose. I'm the head of the department of vascular surgery in AZSint Blasius Hospital in Dendermonde, Belgium. And I want to discuss today with you the PRIZER study with the Renzan™ Stent.

**Unmet Need in Patients with PAD**

Yes, right up to now I think that the accent is most on drug-eluting technologies. So I was asking myself, is there, in 2022, still a place for a modern generation of bare metal stents. And if you are looking carefully to the literature, and you are listening here on this Congress to the presentations, you see that, for instance when you are using drug-coated balloons in very complex lesions, that you need a high rate of bailout stenting with bare metal stents. On the other hand, we learned yesterday also something about the local toxicity of of the potential local toxicity of paclitaxel. So in some indications, some situations potentially it's better to use a bare metal stent. And so based on this, I think there is definitely a place, a need for modern generation of nitinol stents; bare metal nitinol stents.

**The Renzan™ Stent**

So the Renzan stent is actually a stent design that is based on the success of the Roadsaver™ carotid stent of Terumo, with some adaptations at the flaring ends, the lengths, the delivery platform and whatever. We are facing today a bare metal stent, a dual-layer micromesh stent. So there is an outer layer, that is an interwoven stent design, but there is also an inter, an inner layer with a micromesh design, also interwoven mesh of nitinol. And so the combination of both is in my opinion, an step in the good direction. First of all, very interesting, it is protecting against distal embolisation. I noticed that more and more people also during PAD treatment they are using distal protection devices, filters. Well, with this stent, the stent itself is actually a protection device. It is an, an monorail system 6 French compatible, .018" Guidewire system. It has some flaring ends proximally and distally, and in terms of visibility, the stent is doing a great job because there are three tantalum markers at the flaring ends, proximally and distally. And there are also two tantalum markers on each site of the micromesh. So visibility is perfect. When you are looking at the radial forces of the stent, it has sufficient chronic outward force, not too much, not to create intimal hyperplasia, but on the other side, we see that in terms of radial resistor force and crush resistance the Renzan stent is doing a great job, better than the majority of the competitors.

**Study Design and Patient Population**

So the, the study design, the PRIZER study is actually a prospective, non-randomized single arm multicenter trial, where the Renzan stent is going to be investigated in 135 subjects. 90 patients will be enrolled in an fem-pop arm, and another 45 patients will be enrolled in an isolated popliteal artery disease cohort. And so the, the follow up time is 36 months. The primary endpoint is on one side in terms of efficacy, primary patency at one year based on duplex ultrasound findings. And on the other hand, we have also a safety primary endpoint, looking at major adverse events, TLR, amputation rates, and death.

**Enrollment and Expectations**

So right up to now, we are enrolling in this PRIZER study. There is 40% of the enrollment completed right up to now What do I expect at the moment as I, I am one of the most important enrollers in the, in the, the trial. My gut feeling is very good. What I've seen, the controls at 30 days, at six months are really looking great And so I'm quite comfortable. Unfortunately, I can even not compare with other bare metal stents due to the specific design of this, of this Renzan stent; it's uncomparable. I'm, I'm really curious to see if, if the results are at least in the area of drug eluting technology results. And that's also for me an open question mark for the near future.