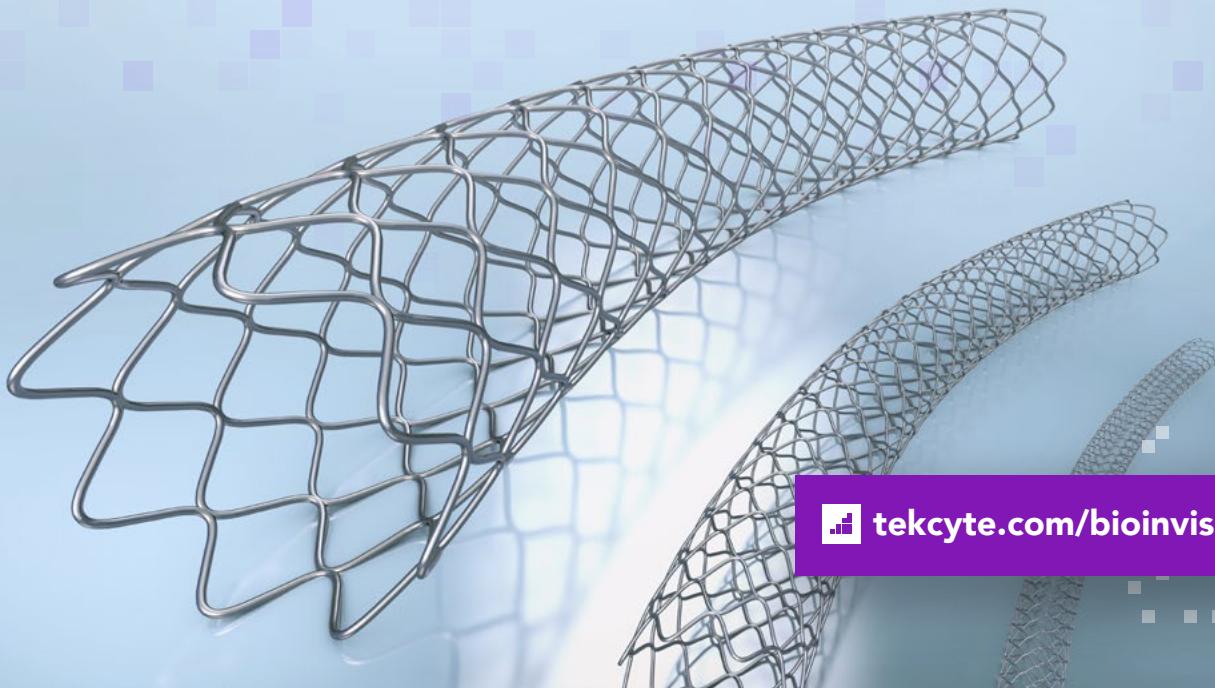




## Superior drug-free vascular device coating

The leading coating technology that prevents  
the build-up of platelets, proteins and cells.



 [tekcyte.com/bioinvisible](http://tekcyte.com/bioinvisible)



## Next-generation device coating technology

Anti-thrombogenic and anti-proliferative vascular coating, creating better outcomes for patients.

BIOINVISIBLE is a highly biocompatible coating that helps to make implantable materials less 'visible' to the body's normal immune defences. The drug-free coating prevents the build-up of platelets, proteins and cells on implanted stents. This coating aims to create safer and more durable vascular devices. The world-leading drug-free stent coating that can be applied to a wide range of metal and polymer materials used in medical devices, at commercial scale.

- Anti-thrombogenic
- Anti-proliferative
- Ultra-thin (<10 nm)
- Extremely stable
- Safe (no cytotoxicity or sensitivity)
- Scalable process
- Environmentally sustainable

### Successful NAMSA Tests

All studies showed no evidence of toxicity or sensitivity associated with exposure to BIOINVISIBLE.



- ✓ ISO Guinea Pig Maximization Sensitization Test
- ✓ ISO Acute Systemic Toxicity Study in Mice
- ✓ ISO Intracutaneous Irritation Study
- ✓ Cytotoxicity Study Using the ISO Elution Method
- ✓ ASTM Hemolysis Study

# Proven & tested results

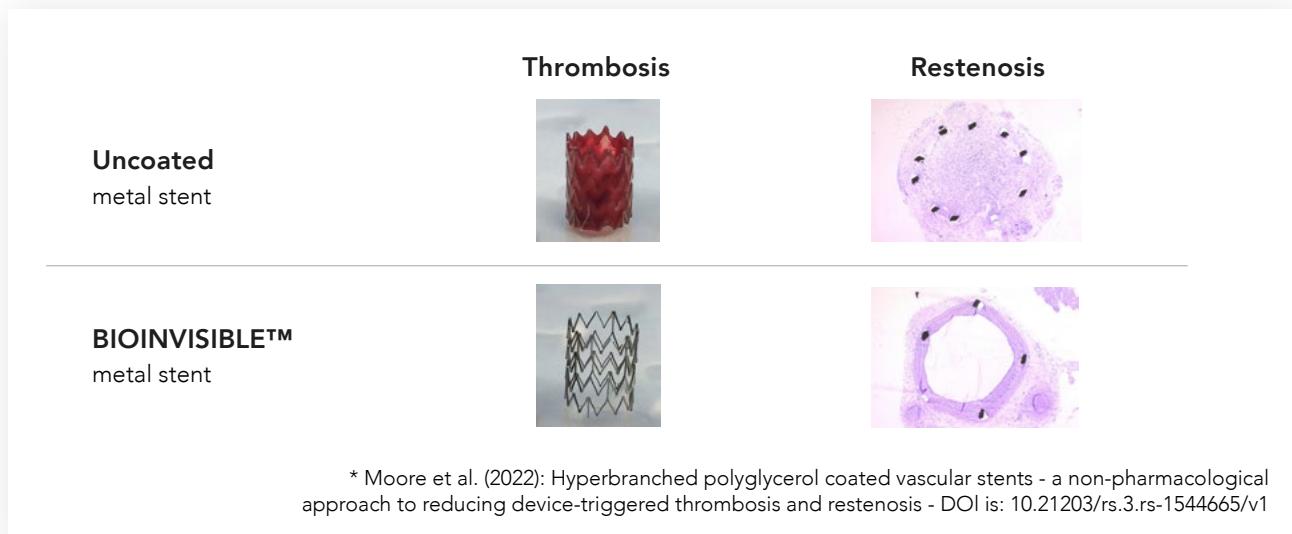
## Dramatically reduces platelet adhesion on vascular stents

Platelets are implicated in the development of stent thrombosis and in-stent restenosis. For a patient receiving a stent, the formation of fibrin clots on the surface of the stent can lead to larger and life-threatening blood clots that can block arteries, requiring emergency surgical intervention.

TekCyte's BIOINVISIBLE coating creates a barrier on the surface of stents, which means the blood can flow normally over the stent surface. This reduces platelet adhesion and activation, greatly reducing the likelihood of a blood clot.

The unique coating has the potential to not only reduce complications from vascular devices, but it may also reduce the need for long-term anti-coagulant therapy for many patients requiring these devices.

Mouse models of restenosis show that BIOINVISIBLE coated stents significantly reduce the level of in-stent restenosis, compared with uncoated stents.



# Safer outcomes & more durable devices

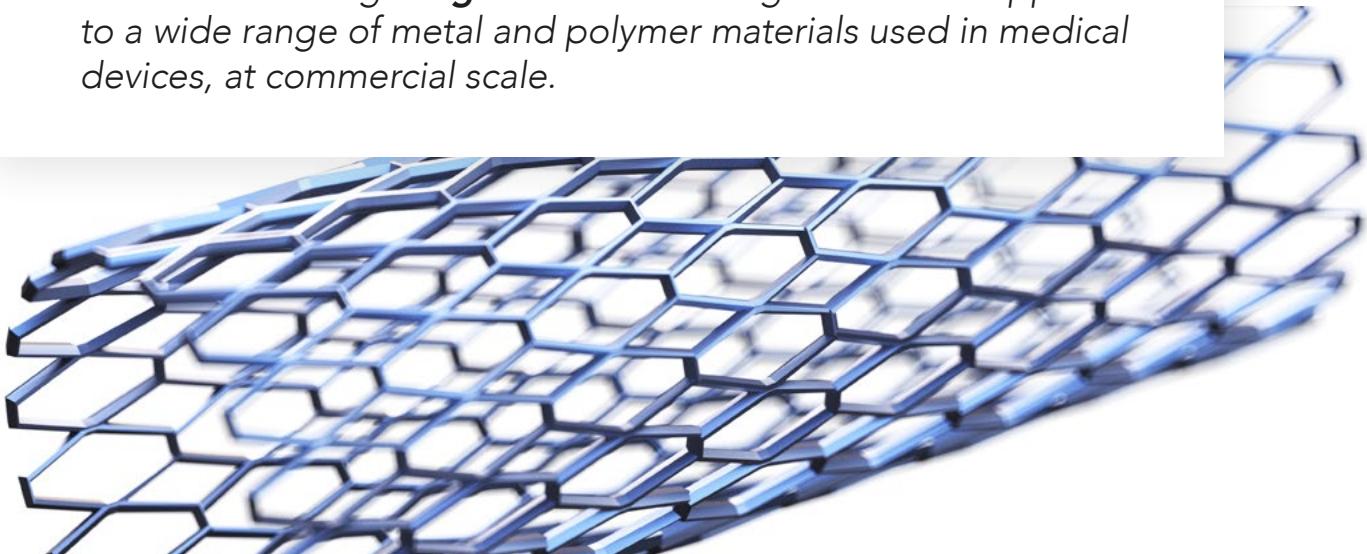
## The current problem

BIOINVISIBLE can help overcome the significant challenges with the high failure rates of stents in the treatment of blocked vessels in peripheral arterial disease. In-stent restenosis can occur in up to 40% of patients and the use of drug-eluting coatings (e.g. paclitaxel) have failed to adequately deal with this complication.

Limitations of drug-eluting stents (DES):

- Benefit of drug is limited to the duration of drug elution
- Increased risk of all-cause mortality
- Increased risk of amputations
- Delayed endothelial repair
- Risk of thrombosis is not reduced

*The world-leading **drug-free** stent coating that can be applied to a wide range of metal and polymer materials used in medical devices, at commercial scale.*



# ■ BIOINVISIBLE™

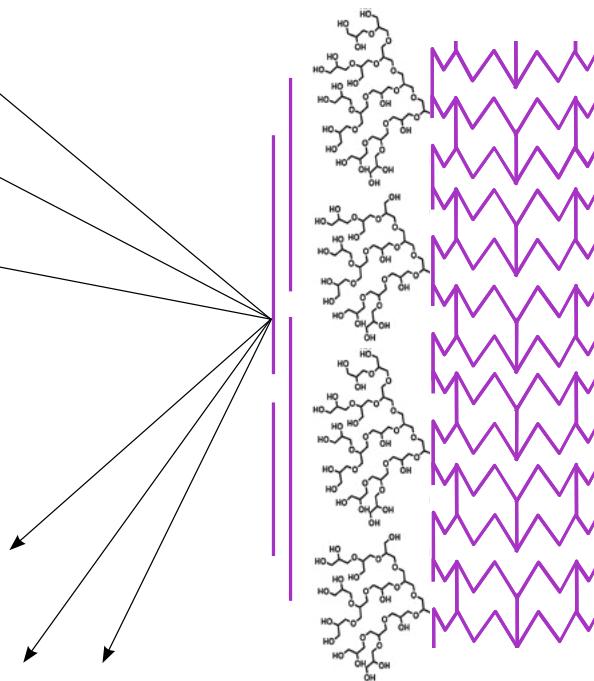
## The BIOINVISIBLE solution

TekCyte offers an alternative drug-free and safe coating: BIOINVISIBLE. It is a hyperbranched polyglycerol polymer coating that acts as a physical barrier on devices. It markedly reduces the adhesion of proteins, cells and other blood components onto implantable biomaterials, which often leads to complications.

**PROTEINS**

**PLATELETS**

**BLOOD CELLS**



The BIOINVISIBLE process has patents granted in the US, Europe, China, Japan and Australia.

# Biocompatible, stable & commercially ready

- The patented BIOINVISIBLE manufacturing process is easily scalable to rapidly meet increasing customer and market demands.
- BIOINVISIBLE is a hydrophilic hyperbranched polyglycerol (HPG) polymer that is applied to biomaterials using a patented coating process.
- Applications may include vascular devices (stents, stent grafts, vascular grafts) and non-vascular devices (cannulas, catheters, reconstructive implants).
- BIOINVISIBLE is chemically bonded to the surface of stents, compatible with ethylene oxide sterilisation and is stable for up to 3 years, stored at room temperature.
- The coating is also non-cytotoxic, allowing for normal repair of the endothelial lining after insertion of a stent.

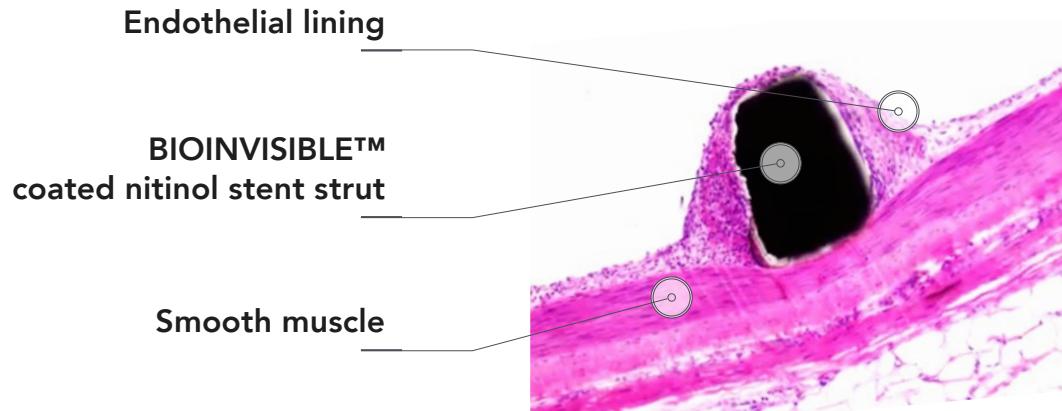


Image: Endothelial regrowth on BIOINVISIBLE™ stent is evident within 5 days after insertion into the artery and vein of an adult pig.



Leading experts in biomaterial science and biology



### **Established Quality** Management System

Industry-leading manufacturing capabilities include state-of-the-art cleanrooms and scalable equipment. Systems are supported by a quality framework aligned to ISO13485.



### **Commercially Scalable** Manufacturing

Manufacturing facilities are equipped with the latest equipment and technologies to facilitate expansion to commercial scale coating processes. Scalability is built into TekCyte's coating process designs.



### **Environmentally** Conscious

Wet chemical processes are eliminated or minimised to be environmentally conscious and sustainable, creating solutions and applications with minimal waste.

Leaders in drug-free coating solutions that improve the safety, performance, and durability of implanted medical devices.

**TekCyte** 

+61 8 8302 3491

info@tekcyte.com

tekcyte.com

