Intrepide

Trapidil Eluting Coronary DES

DELIVERY, EFFICACY, SAFETY, STABILITY

Intrepide is a coronary DES, which elutes the drug Trapidil. The system is mounted on the Nimbus Pico rapid exchange catheter platform.

Trapidil has been shown in a number of clinical studies to demonstrate four primary modes of action when given orally:

- Anti-proliferative
- Vasodilator
- Anti-thrombotic
- Anti-inflammatory

Trapidil was initially developed in 1971. The drug was initially designed as a vasodilator. However, over the past few decades, studies have found Trapidil to be a potent inhibitor of platelet aggregation and activation, vascular smooth muscle cell proliferation, and monocyte/macrophage migration and activation, thereby making it a potentially potent anti-restenotic agent.

PRODUCT FEATURES

Delivery - The Intrepide is mounted on our Nimbus Pico catheter, which allows for better access to the most complex lesions. The overall profile is the lowest of any DES currently on the market today.

Efficacy - Intrepide has four modes of action which are, anti-inflammatory, anti-thrombotic, anti-proliferative and acts as a vasodilator. These combined make Intrepide one of the most interesting DES developments since their first clinical introduction.

Safety - Results from the DESTINY I trial demonstrate that Product related MACE at 30 days is 0%, Target lesion revascularisation is 5.2% at 180 days and there was no Subacute Thrombosis at 180 days, making Intrepide one of the safest stents on the market

Stability - The Intrepide is a highly temperature stable drug, meaning that it can be used in any ambient atmosphere likely to be encountered in all climates.

CLINCAL EVALUATION DATA

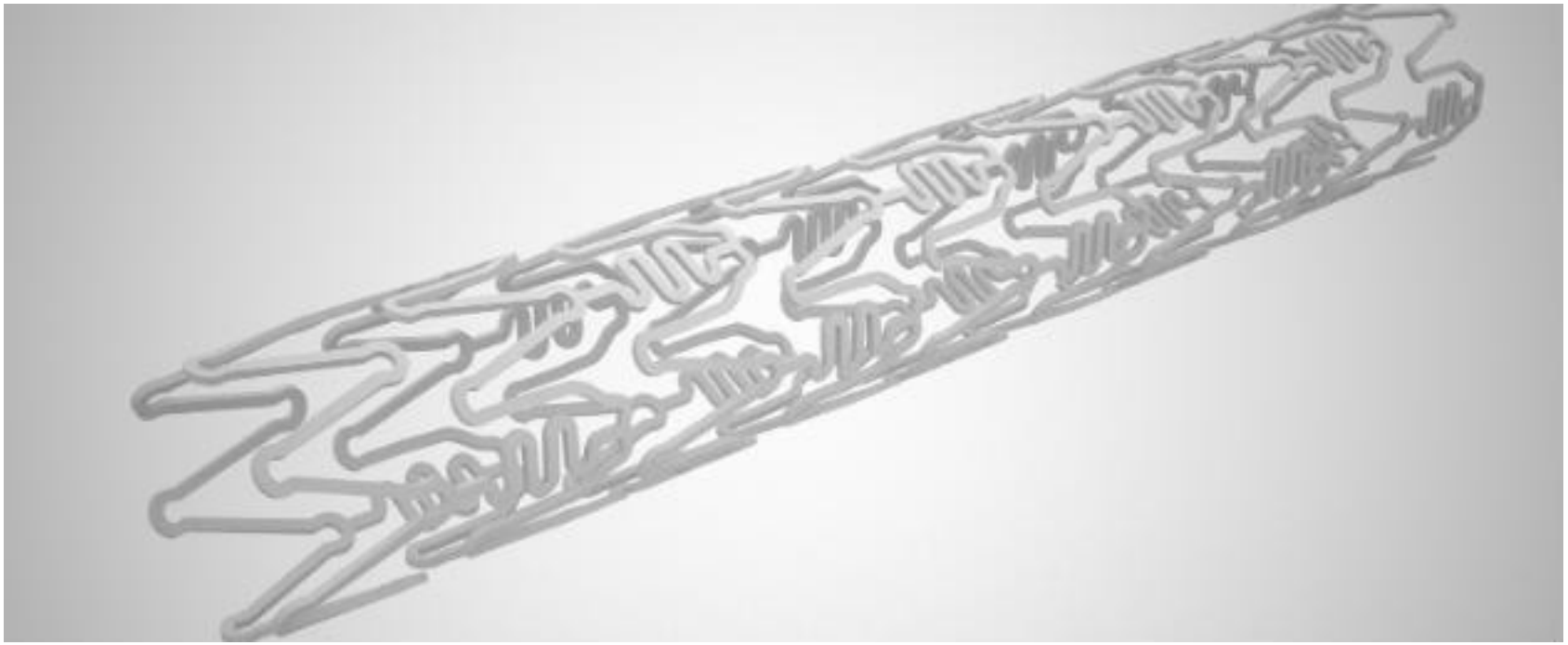
The case for the investigation of the use of Trapidil in a Drug Eluting Stent includes the following points set out below:

- MAPK Inhibitor - including PDGF, FGF inhibitor - which also inhibits SMC proliferation in vitro and intimal proliferation in vivo.
- Additional anti-platelet and vasodilatory effects
- Anti-inflammatory effects
- Negligible toxicity
- Effective incorporation into a drug /polymer coating on a stent for sustained release and effect at the site

Results from the Destiny trial are summarised below:
• Device success in 98%
• Procedural success in 100%
• No MACE at 30 days
• No Sub acute Thrombosis at 180 days
• No MI at 180 days
• In-stent late loss of 0.72(±0.49) is less than in historical bare metal stents ($p<0.01$), meeting the primary objective
• Target lesion revascularization in 6.2% at 180 days

This first in man study has demonstrated excellent safety and clinical outcomes following use of the ICON Trapidil Drug Eluting Coronary Stent

Conclusion: Icon Destiny DES significantly reduces late loss compared to historical BMS controls. It also demonstrates excellent deliverability of the stent. Despite relatively high late lumen loss (LLL), the TLR rate was quite acceptable. There was no MACE at 30 days and no sub acute or late stent thrombosis at 180 days confirming the safety of the stent.



Intrepide Part Numbers

Inflated Balloon Diameter	8mm	12mm	16mm	Stent Lengths 20mm	24mm	28mm	32mm
2.50mm	39225008	39225012	39225016	39225020	39225024	39225025	39225032
2.75mm	39227508	39225712	39227516	39227520	39227524	39227528	392275352
3.00mm	39230008	39230012	39230016	39230020	39230024	39230028	39230032
3.50mm	39235008	39235012	39235016	39235020	39235024	39235028	39235032
4.00mm	39240008	39240012	39240016	39240020	39240024	39240028	39240032