No-React® Injectable BioPulmonic Valve

Benefits

- **Fewer operations** required in the future for the patient owing to greater longevity of the No-React® NRIP device than standard glutaraldehyde treated devices
- **Faster recovery** and a lower risk of post-operative morbidity
- **Shorter operating times**
- **Cost savings** – theatre costs are lower, no CPB consumables, post-operative care is reduced

Patients born with Tetralogy of Fallot or other forms of pulmonary valve malfunction will require early surgical intervention. Later in life they will need pulmonary valve replacement with either a homograft or a tissue valve. However standard glutaraldehyde treated tissue has limited durability and is prone to infection, rejection, adhesions, calcification and thrombosis, requiring repeat operations in the future.

The No-React® Injectable Pulmonic Valve (NRIP) is the only device on the market that offers the combination of a highly durable, infection, calcification and dilatation resistant tissue valve with a percutaneous implantation system that avoids the risks associated with repeated cardiopulmonary bypass (CPB) supported operations.

- Large-diameter hybrid percutaneous implantation; **no bypass necessary**
- Enables Primary Repair of Tetralogy of Fallot
- A full range of sizes from 15 - 31 mm is available to match patient morphology
- No reported structural failures or stent fracture over 7 years
- 7 years’ experience - longest of any transapical heart valve

There is strong evidence from off-pump coronary artery bypass grafting that avoiding CPB can reduce the incidence of post-operative atrial fibrillation, blood loss, renal dysfunction and myocardial cell injury compared to conventional CPB surgical strategies.

The NRIP is implanted without CPB, reducing iatrogenic harm to the heart and systemic inflammation which, in turn, are expected to result in faster recovery and to reduce the risk of a major post-operative complication.

“The new, self-expanding, catheter-based pulmonary valve [The No-React® Injectable Pulmonic] is easy to implant via an Antegrade (RVOT, RV) or retrograde approach (PA) even in dilated RV outflow tracts. The procedure can be done without CPB under echocardiographic guidance.”

Schlensak et al
| Materials | Porcine Pericardium Sleeve  
| Porcine Valve  
| Nitinol Stent |
|---|---|
| Expected Implanted Product Lifespan : Primary | Used until patient outgrows the device |
| Expected Implanted Product Lifespan : Secondary | Used without intervention for as long as 7 years |
| Delivery System | Self-expanding stent introduced by trocar system |
| Eligible Patients | Any patient with failing pulmonary conduit or Right Ventricular Outflow Tract (RVOT) insufficiency of almost any type |
| No-React® Treated Tissue |  
- Reduced toxicity  
- Enhanced biocompatibility  
- Lower rates of infection, adhesion, and calcification  
- Promotion of endothelial lining |
| Indications |  
- Pulmonary Stenosis  
- Severe regurgitation  
- Primary: Tetralogy of Fallot (TOF) repair  
- Secondary: Treating consequences of original TOF repair |
| Bioprosthetic Design |  
- Similar to homografts in performance with wide range of sizes  
- Avoids need of lifelong anticoagulant use related to mechanical valves  
- Percutaneous, off-pump large diameter injectable valve  
- External fixation prevents migration  
- No size limitations  
- No complex imaging required  
- Not restricted by the limitations of transcatheter methods and inflexible stent designs  
- 0% stent fracture rate  
- Reduces the need for blood transfusions |
| Nitinol Stent Design |  
- External fixation with sutures is easily palpable externally making suture fixation relatively simple |

**Contact**

For customer services and for any further information on the NRIP or any of the other products in the BioIntegral Surgical No-React® range please contact:

Pierson Surgical Ltd

01225 766632 or sales@piersonsurgical.com

**Clinical Papers**

Berdat et al, 2006, J Thorac Cardiovasc Surg., "Off-Pump pulmonary valve replacement with the new Shelhigh Injectable Stented Pulmonic Valve"

Marianeschi, 2008; Ann. Thorac. Surg,"Pulmonary valve implantation with the new Shelhigh injectable Stented Pulmonic Valve"


Schlensak et al 2011, Article in Press prior to European Journal of CardioThoracic Surgery "Implantation of a catheter-based self-expanding pulmonary valve in congenital heart surgery: Results of a pilot study"