Pierson Surgical Ltd.

Innovative, High Quality Surgical Products

No-React® Injectable BioPulmonic Valve

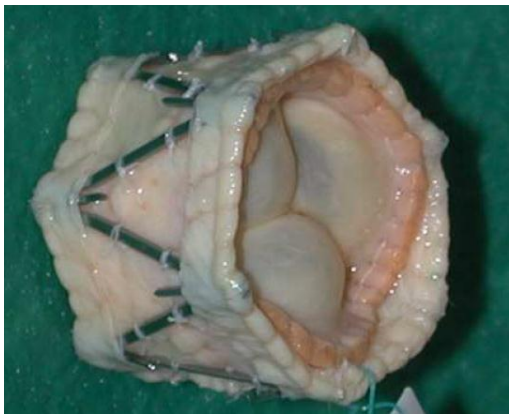
Benefits

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



- Large-diameter trocar 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**

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 trocar implantation system that avoids the risks associated with repeated cardiopulmonary bypass (CPB) supported operations.

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

CAUTION: Refer to the Instructions For Use provided with each device for complete information regarding indications for use, contraindications, warnings, precautions and potential complications.

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"

Schreiber, et. al, 2006; Ann. Thorac. Surg.,"Implantation of a Prosthesis Mounted Inside a Self-Expandable Stent in the Pulmonary Valvar Area Without Use of Cardiopulmonary Bypass"

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

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