A PROCESS OF MANUFACTURING A HEART VALVE MADE OF A POLYMERIC MATERIAL AND THE HEART VALVE THEREBY OBTAINED

CHALLENGE
The normal physiological function of a heart valve (VC) is to ensure unidirectional blood flow through regular opening and closing at each cardiac cycle. This vital function can be altered by heart valve diseases, which can lead to either blood flow obstruction (stenosis) or retrograde blood loss (regurgitation) or to both conditions. Valve replacement therapy is a standard treatment in severe symptomatic conditions. The principal requirements of replacement heart valves are the efficient function and long-term durability without the need for anticoagulation therapy, coupled with the ability to be accommodated in many different subjects. Currently, there are two different types of heart valve prostheses: i) mechanical valves with long duration, not requiring re-intervention, and not subject to structural failure but requiring chronic anticoagulant therapies to avoid thromboembolic complications; ii) biological valve prostheses made with animal pericardium modeled and sutured on supporting structures (stents), reproducing the functional and biomechanical characteristics of the native valve, inducing minor thromboembolic complications but usually requiring to be replaced 10-15 years after implantation due to calcification problems or damage. Polymeric heart valve prostheses have been investigated as a valid clinical alternative with low production costs.

SOLUTIONS
A process to obtain a polymeric heart valve has been developed and proven to generate an object of similar geometry, reproducing the physiological fluido-dynamic conditions and a morphology able to reduce to a minimum the thromboembolic complications. The valve is a single body integrated with the support stent and is made of an elastomeric biomaterial highly hemo-compatible and durable. This new material is processed by 3D-spray technology in a single and reproducible mono-block which guarantees the necessary fatigue/resistance characteristics. Preliminary animal studies have shown the valve to be highly compatible and likely not requiring chronic anticoagulant treatment. Its reliability and duration suggest the implant on humans likely to be a permanent prosthesis (at least 15 years).

APPLICABILITY
The present valve prosthesis is an aortic valve that could be implanted in young and old patients by traditional surgery techniques. The valve is characterized by a reproducible and short process of production that could be automated thus reducing time and production costs if compared to the products available on the market.

COMMERCIAL OPPORTUNITY
• We are actively looking to raise funds to support running the regulatory pre-clinical package and the entry into humans.
• Alternatively both Humanitas and CNR are available to license the asset.

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PATENT SITUATION
Grated European patent (EP 3157467) and granted patent in China (CN201580032525)

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