



TaurusNEXT[®]

全球领先“非醛交联”经导管主动脉瓣系统

产品介绍

潘孔荣 先生
沛嘉医疗 首席运营官

至善尽心 敬畏生命

免责声明

- The documents, opinions and materials presented in this presentation (the “Document”) have been prepared by Peijia Medical Limited (the “Company”) for use in presentations by the Company and does not constitute a recommendation regarding the securities of the Company. You fully understand that the Document is being made available on a confidential basis and subject to the following provisions. The contents of this Document have not been reviewed by any regulatory authority in any jurisdiction. The distribution of this Document in certain jurisdictions may be restricted by law, and the recipients into whose possession this Document comes should inform themselves about, and observe such restrictions. By accessing this Document, you are agreeing (i) that you have read and agree to comply with the contents of this notice and disclaimer and (ii) to maintain absolute confidentiality regarding the information disclosed in this Document.
- This Document has not been independently verified and is not intended to form the basis of any investment decision. It does not constitute an offer or invitation to sell, or any solicitation of any offer to subscribe for or purchase any securities in any jurisdiction in which the making of such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction or would not otherwise be in compliance with the laws and regulations of such jurisdiction, and nothing contained herein shall form the basis of any investment decision, contract or commitment whatsoever. This Document contains no information or material which may result in it being deemed (1) to be an advertisement, invitation or document containing an advertisement or invitation falling within the meaning of section 103 of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) (the “Securities and Futures Ordinance”) or (2) in Hong Kong to have effected an offer to the public without compliance with the laws of Hong Kong or being able to invoke any exemption available under the laws of Hong Kong, and is subject to material change without notice.
- The securities of the Company have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the “U.S. Securities Act”), or under the laws of any state of the United States. This Document does not constitute or form a part of any offer or solicitation to purchase or subscribe for securities in the United States and is not for distribution and may not be distributed, directly or indirectly, in or into the United States (including its territories and possessions, any state of the United States and the District of Columbia). The securities of the Company will not be offered or sold in the United States except pursuant to an exemption from, or in a transaction not subject to the registration requirements of the U.S. Securities Act. There will be no public offer of the Company’s securities in the United States.
- This Document and the information contained herein as well as information presented orally or otherwise are strictly confidential and must be treated as such. Neither the information contained in this Document nor any copy hereof may be, directly or indirectly, taken or transmitted into or distributed in the United States, Canada, Australia, Japan, PRC, Hong Kong or any other jurisdiction which prohibits the same except in compliance with applicable securities laws. Any failure to comply with this restriction may constitute a violation of U.S. or other jurisdiction’s securities laws. Upon request, the recipient will promptly return this Document and any other written information made available in the presentation, without retaining any copies.
- This Document does not purport to be comprehensive or to contain all the information that a recipient may need in order to evaluate the Group. No representation, warranty or undertaking, express or implied, is given and, so far as is permitted by law, no responsibility or liability is accepted by any person (for the avoidance of doubt, including but not limited to, the Company and its affiliates, controlling persons, directors, officers, partners, employees, agents, representatives or advisers of any of the foregoing), with respect to the accuracy, reliability, correctness, fairness or completeness of this Document or its contents. The information communicated in this presentation contains certain statements that are or may be forward looking. These statements typically contain words such as “will”, “expects”, “intends”, “plans to” and “anticipates” and words of similar import. These forward-looking statements reflects the current view of the Company with respect to future events are based on a number of assumptions about the Company’s procedures and factors beyond the Company’s control and are subject to significant risks and uncertainties, and, accordingly, actual results may differ materially from these forward-looking statements. In particular, but without limitation, no representation or warranty is given as to the achievement or reasonableness of, and no reliance should be placed on, any assumptions, projections, targets, estimates, forecasts or any forward-looking statements contained in this Document. Each of the Company and its affiliates, controlling persons, directors, officers, partners, employees, agents, representatives or advisers of any of the foregoing assumes no obligation to update or otherwise revise these forward-looking statements for new information, events or circumstances that occur subsequent to such dates. None of the Company and any of its affiliates, controlling persons, directors, officers, partners, employees, agents, representatives or advisers of any of the foregoing shall have any liability (in negligence or otherwise) in respect of the use of, or reliance upon, the information contained herein by you or any person to whom the information herein is disclosed.
- In furnishing this Document, the Company and its affiliates undertake no obligation to provide any additional information or to update this Document or any additional information or to correct any inaccuracies which may become apparent.

设计目标

- 提高产品寿命
- 提高生物相容性
- 提高使用方便性

核心技术

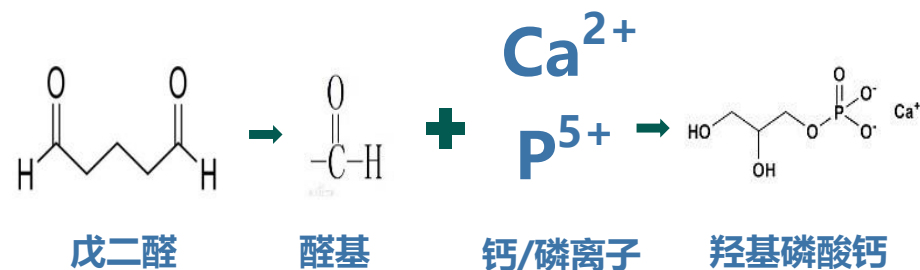
- 心包非戊二醛交联技术
- 超低温真空干燥技术
- 心包表面修饰技术
- 心包纤维方向辨识技术

生物组织失活

- 新陈代谢停止 – 组织松散
- 组织开始降解 – 组织腐败

交联处理的目的

- 停止组织腐败 – 清除降解酶
- 建立组织间永久化学键绑定



评价方法	试验结果	
MTT试验 (GB/T 16886.5-2017)	100% 样品浸提液细胞活力为 75.2%	
皮肤致敏试验 (GB/T 16886.10-2017)	致敏阳性率 0%	
皮内反应试验 (GB/T 16886.10-2017)	样品极性浸提液皮内反应计分为 0	
急性全身毒性 (GB/T 16886.11-2011)	未观察到临床毒性症状，且样品组反应不大于阴性对照组反应	
亚慢性全身毒性 (GB/T 16886.11-2011)	试验样品组和阴性对照组各时间点体重、器官重量、器官/体重比、血液学数据、临床生化数据和组织病理学结果均无明显差异	
遗传毒性 (GB/T 16886.3-2019)	体外哺乳动物细胞基因突变试验	与阴性对照相比未见突变频率明显偏高，且无剂量相关性增高趋势
	鼠伤寒沙门氏菌回复突变试验	样品浸提液回变菌落数与阴性对照相比无明显增加，且无剂量相关性增高趋势
	哺乳动物体外细胞染色体畸变	样品浸提液各浓度组的染色体畸变细胞率为0%，与阴性对照组相比无明显差异
热原试验 (GB/T 16886.11-2011)	注射后3只新西兰大白兔中最高个体升温值为0.2℃，且3只兔升温总值为0.4℃	
植入后局部反应试验	样品肌肉植入部位组织结构未见异常，组织病理学提示26周为轻微刺激反应	

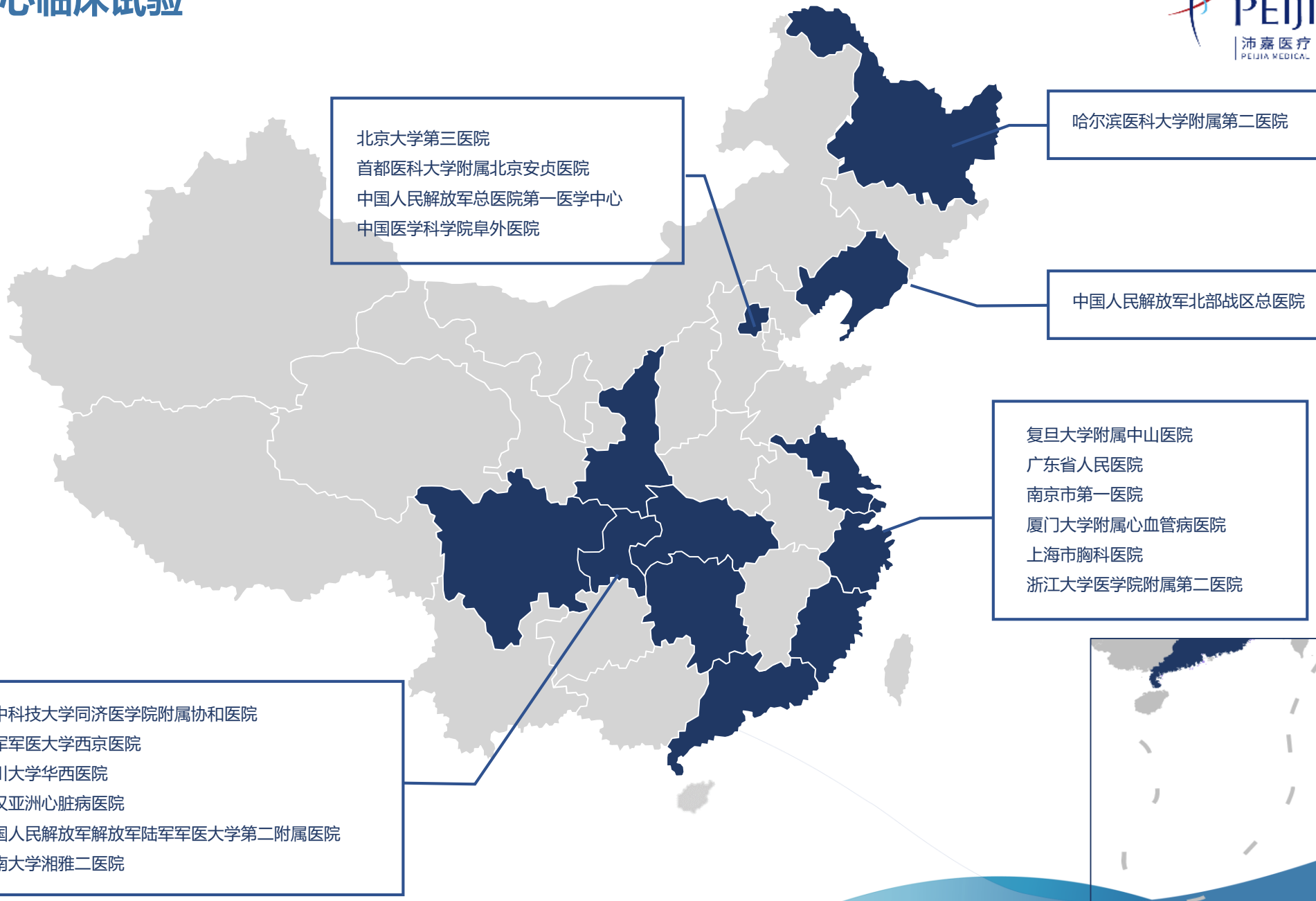
产品性能试验结果

生物相容性	非戊二醛处理的样品在人脐静脉内皮细胞和HUVEC培养中都表现出更高的内皮细胞相容性
生物安全性	非戊二醛处理的样品血液相容性更高、免疫原性更低、抗钙化性能更强、灭病毒效果更优
交联效果	非戊二醛处理的样品抗降解性能更强，内部交联度更高
交联后微观结构	非戊二醛工艺保留了胶原的螺旋结构及更加平滑的表面
复水后即刻血液动力学	复水后，开口面积高于ISO5840要求，总反流百分比低于ISO5840要求，即刻血液动力学指征良好
耐久性能	经4亿次耐久测试后，开口面积高于ISO5840要求，总反流百分比低于ISO5840要求，血液动力学指征良好
动物长期植入	瓣叶表面基本无血栓沉积、未见钙化、未见血管翳增生

协调研究者(PI)



葛均波 院士
复旦大学附属中山医院



研究目的

通过实施前瞻性、多中心、单组目标值研究评价TaurusNXT®经导管主动脉瓣系统用于治疗重度主动脉瓣钙化性狭窄的安全性及有效性

研究设计

依据 NMPA2019 年发布的《经导管植入式人工主动脉瓣膜临床试验指导原则》的建议，采用前瞻性、多中心、单组目标值设计，计划入组 150 例受试者

注册试验阶段

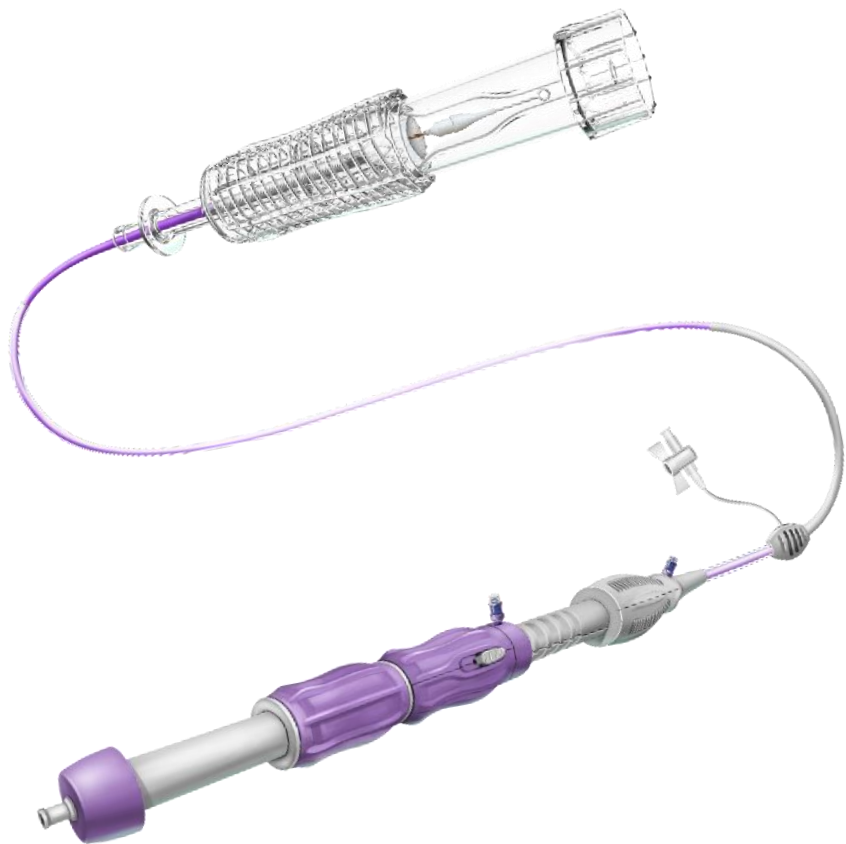
主要指标（主要终点）：12个月的累积全因死亡率

次要指标：器械成功率(术后即刻)，手术成功率，心功能改善（NYHA心功能分级），患者术后生活质量

安全性指标：不良事件发生率，主要不良心脑血管事件(MACCEs)的发生率，主要不良瓣膜相关事件(MAVREs)的发生率，出血发生率，急性肾损伤发生率，血管并发症发生率，其它 TAVR 相关并发症发生率，瓣膜功能

追加访视阶段

在完成术后12个月的随访后，追加随访到术后5年，以评价长期的安全性和有效性



- 目前入组5例的30天临床数据初步表明，TaurusNXT®经导管主动脉瓣系统是安全有效的
- TaurusNXT® 采用国际领先的**非醛交联**瓣叶处理技术和**低温干燥**处理技术，同步优化了支架结构和输送系统，在瓣膜锚定、封堵、血流动力学改善以及术者操控性等方面都有进一步提升
- TaurusNXT®经导管主动脉瓣系统采用**干瓣预装载**设计，降低手术准备时间，更加简单便捷



感谢聆听

沛嘉医疗有限公司

All rights reserved