# History of our valvuloplasty balloon catheter for Pediatric patients

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# Development history

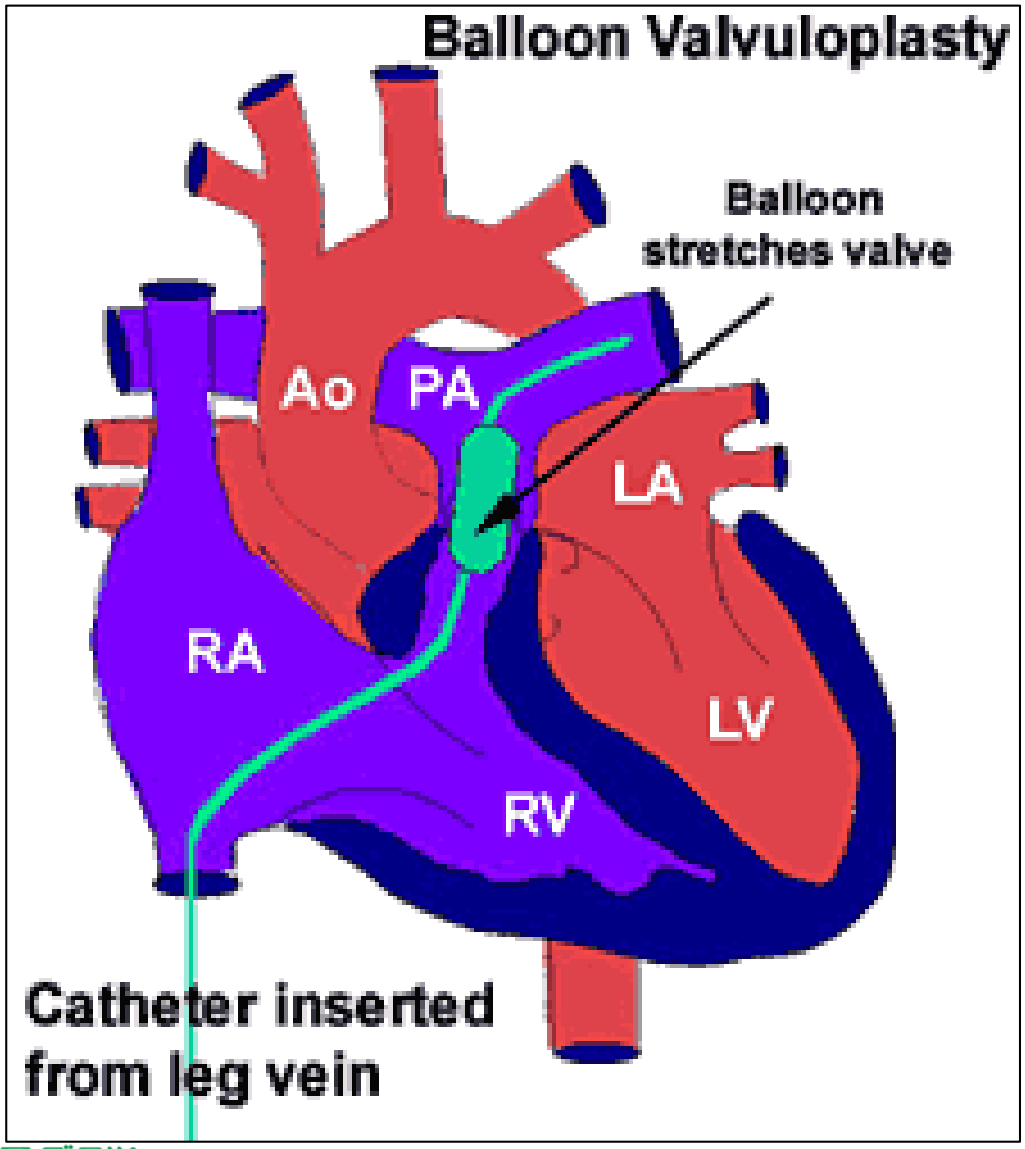
2010年　Request for pediatric valvuloplasty catheter from Dr.Tomita

2011年　First application to PMDA

2014年　Approved by PMDA

2015年　Start marketing

# Balloon Valvuloplasty

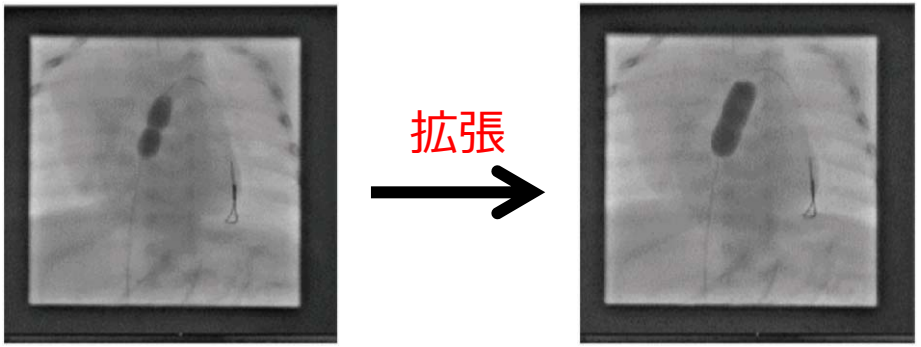


# Technical challenge

- 3Fr Sheath for the 10 mm balloon
  Change of balloon material and wrapping method

- Short tip and short balloon shoulder
  Reduce the damage on the vessel and heart wall

- Balloon stability while dilatation
  Good stability at valve during balloon dilatation because of the change of balloon material to polyamid



# Regulatory challenge

- Original Plan

  Apply as a category of approved PTCA or PTA balloon because of lower RBP and similar structure

- Change of PMDA regulation

  Predicate device is approved by old law.
  Retry under the renewed regulation.

- Repeated inquiry

  Repeated inquiry for safety and utility.

  →Consult doctors

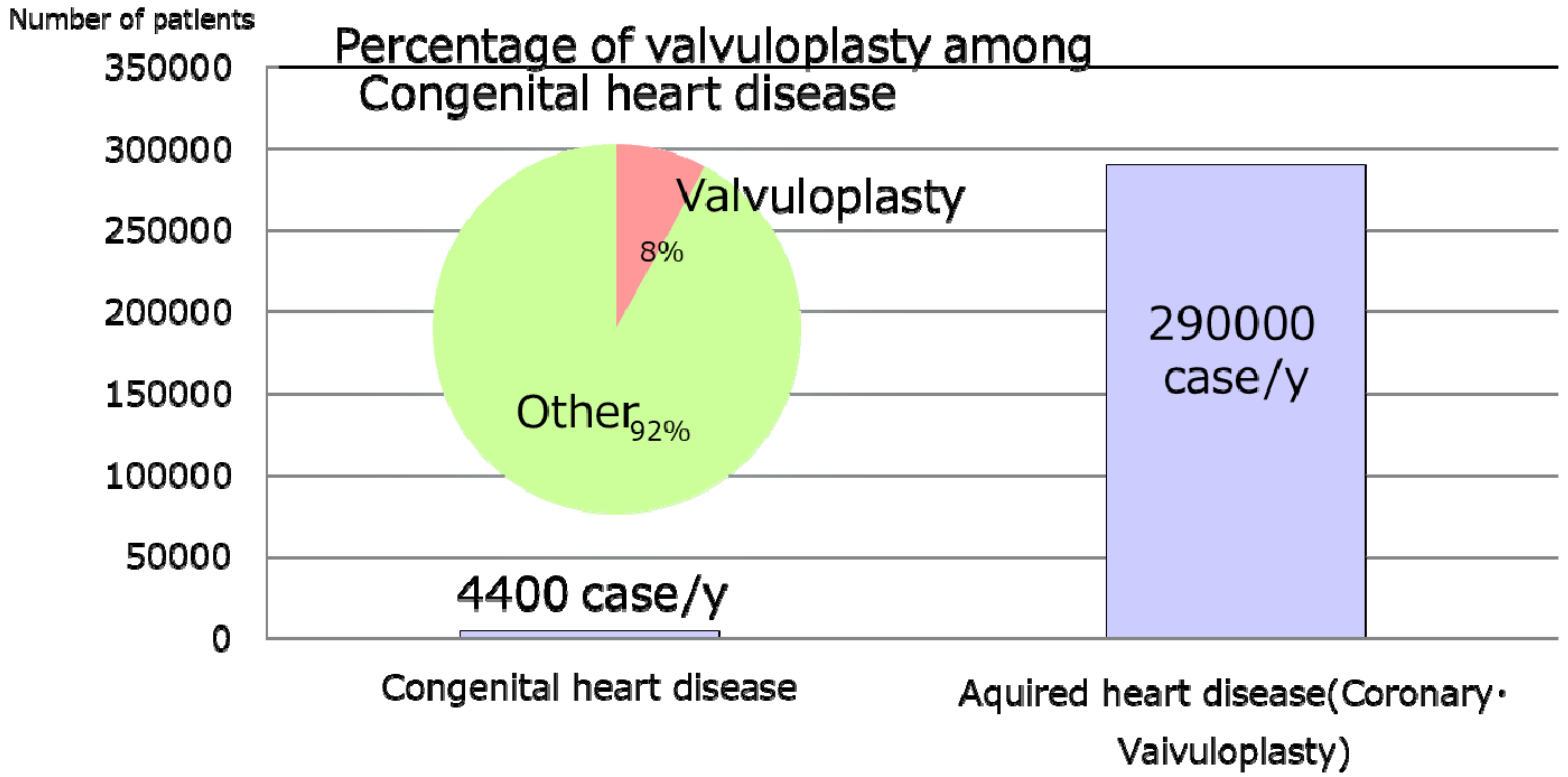
  →Preparation of valve model of pediatric size

  →Repeated evaluation with doctors

# Marketing challenge

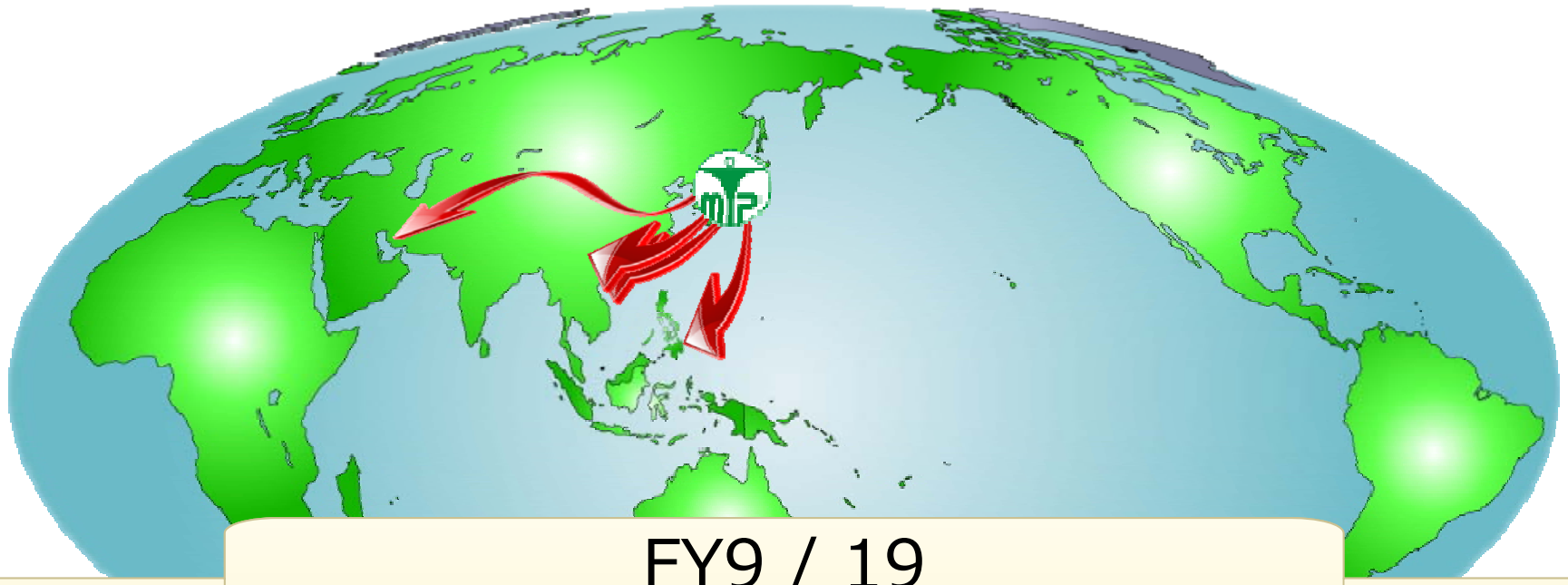
・The market size is overwhelmingly smaller than that of adults, making it difficult to recover the investment.

・ Because development costs are limited, the product lineup must be limited.




Ref : Yano research institute market report 2018, Journal of JPIC(Vol.3,No.2(2018):43-55)

# Export status



FY9 / 19
Domestic　156
overseas　839
（Vietnam・Philippines・Thailand・Iran）

# Through the development experience

- The reimbursement price for adult and pediatric catheters is the same.
- Common standards for approval in the United States, Europe, China, and Japan are desired.
- It is also necessary to create guidelines for product safety testing.