History of our valvuloplasty balloon catheter for Pediatric patients
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.

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.