

Master-Thesis Engineering, Fachgebiet Medical Engineering

Design and Development of a new Balloon Forming Product in a highly regulated Environment

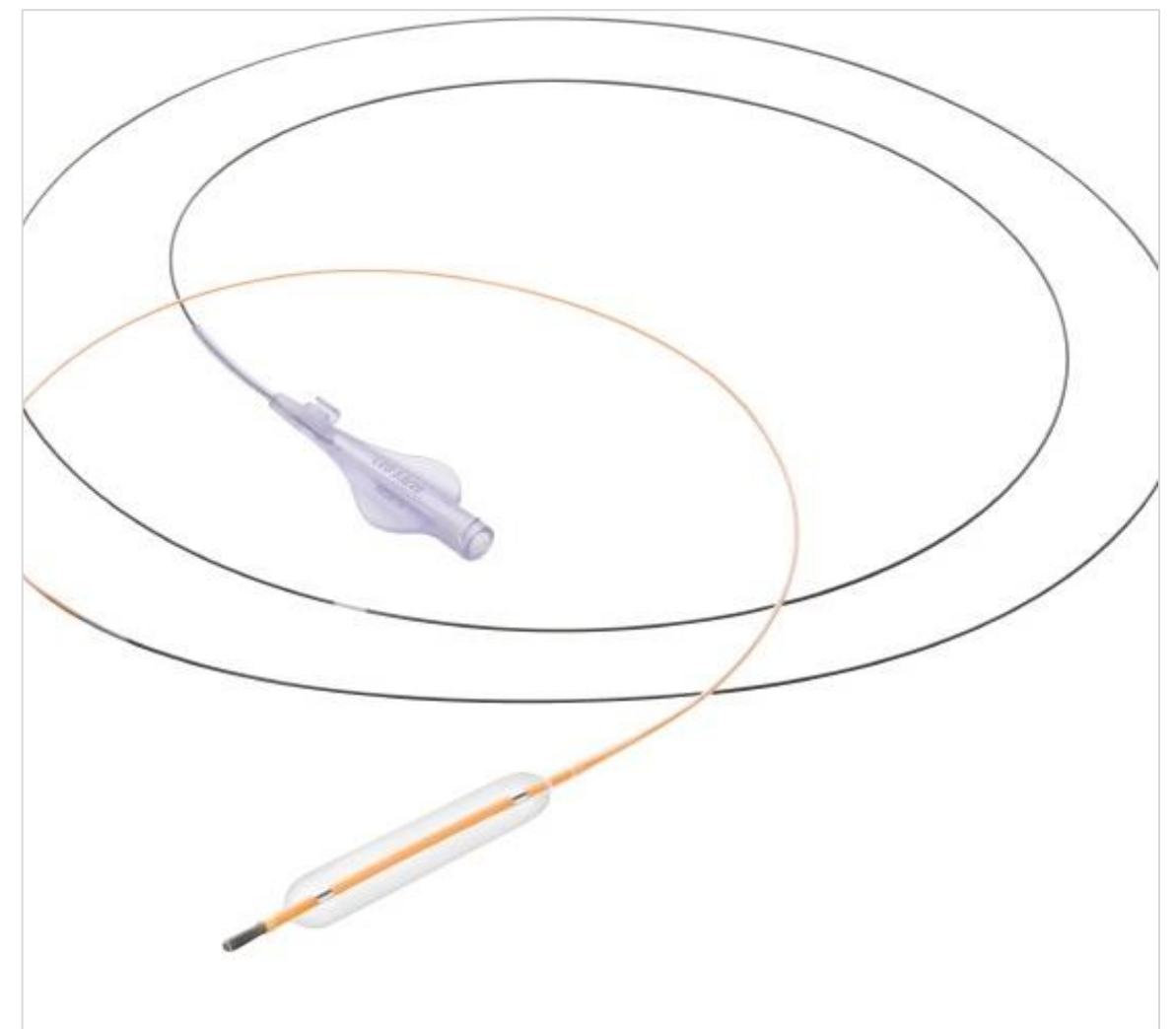
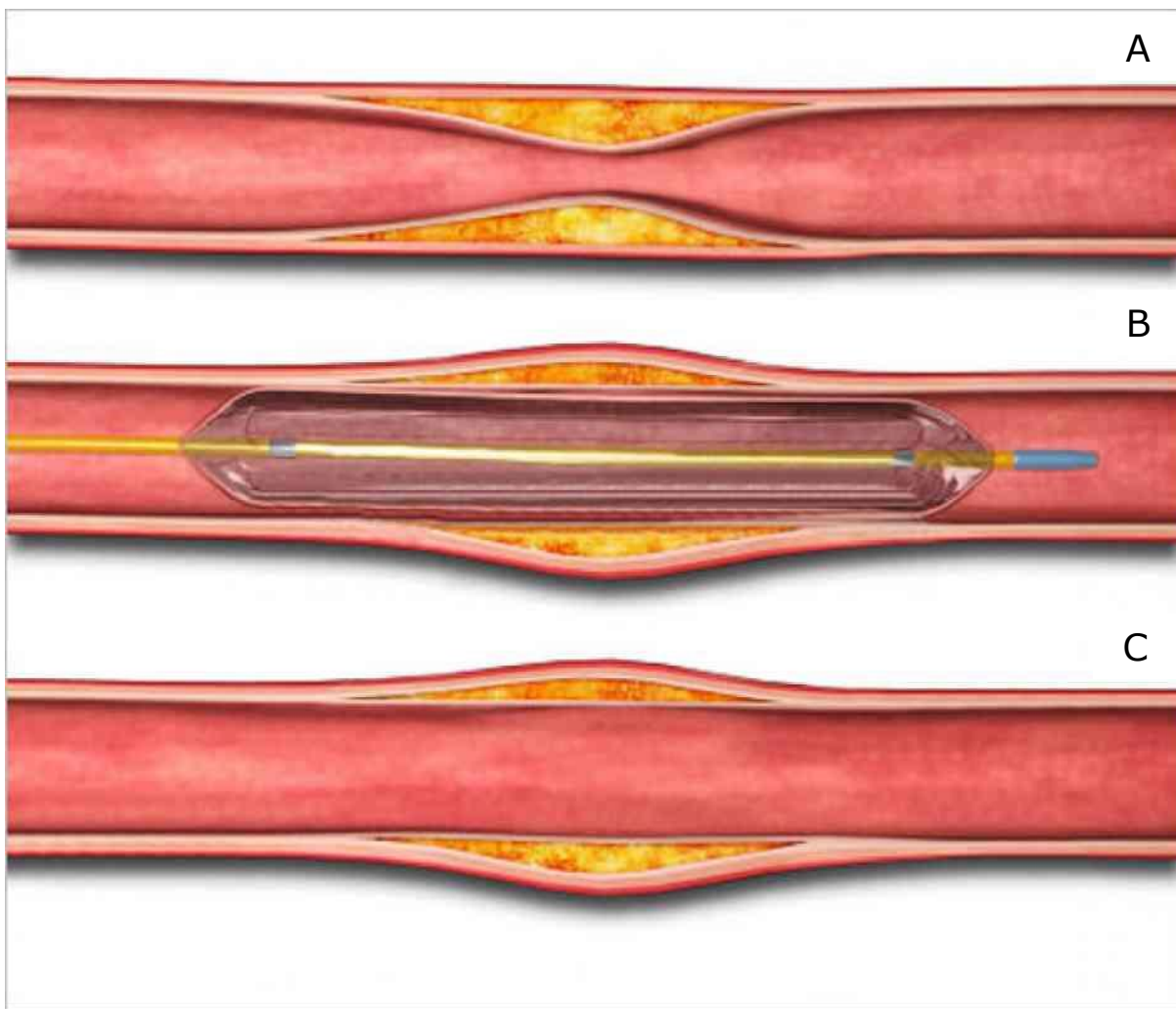


Figure 1: Coronary Balloon Angioplasty Procedure (A) Narrowed Coronary Artery (B) Expanded Balloon (C) Opened Artery
[Source: <https://www.conicvascular.com/balloon-angioplasty>]

Figure 2: Coronary Balloon Catheter (Pantera Leo)
[Source: biotronik.com]

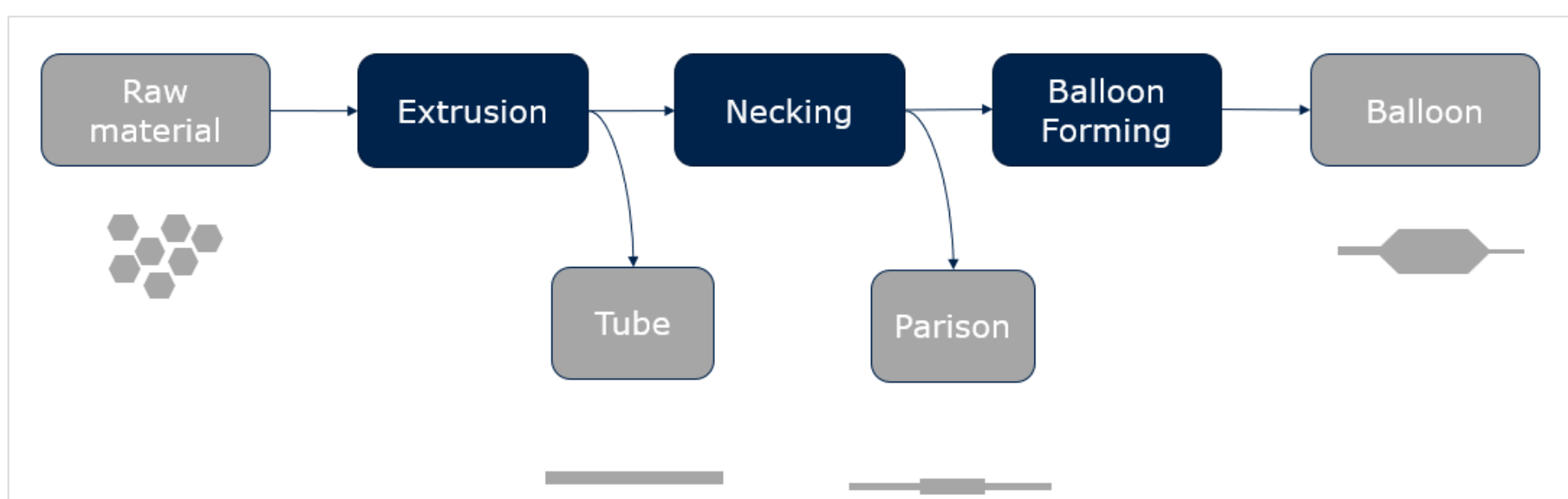


Figure 3: Balloon Manufacturing Process

Problem Definition:

Within the scope of the master thesis, a new class III product and the related process were to be developed on a new manufacturing equipment. The focus of the thesis is on the manufacturing processes of coronary balloon catheters (see figure 1 and 2) in extrusion and stretch blow molding. No commercial products have yet been produced on the new equipment, which is why the process development should form a base not only for this product but also for all further products.

The product had to meet defined design specifications and performance criteria. The product and process development took place under regulatory requirements in the clean room environment.

Solution Concept:

The solution design includes an analysis of the entire process flow from the raw material to the balloon (see figure 3). The balloon is subsequently processed into a balloon catheter. By design of experiments, reliable process parameters were determined in the stretch blow molding process and the product was optimized.

Furthermore, regression analysis was used to investigate influencing factors in the manufacturing processes and evaluate models for optimizing the design specifications and performance criteria. These findings expand the field of knowledge in the practical experience and literature for all future products.

The product developed through the solution concept also offers a great advantage from the clinical aspect. By an expanded product portfolio, new balloon sizes can be offered on the market, which provides an enhanced benefit for the end user in the clinic.

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