Automated Production of Wire Based Stent Implants

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1. Introduction

According to the World Health Organization (WHO), cardiovascular disease and cancer will be the leading causes of death in the upcoming years. In 2016, cardiovascular diseases are the leading cause of death with 17.9 million cases, followed by cancer with 9 million cases. The main reasons for the increase in diseases worldwide are population growth and rising life expectancy. The development of atherosclerosis in vessels as well as tumours in or on organs can lead to partial to complete occlusion and thus to the failure of vital bodily functions. This results in a growing demand for stent implants to open the lumen. In line with the increasing clinical demand, stent implants are used in diverse medical specialties. In 2019, according to the "Bundesinstitut für Arzneimittel und Medizinprodukte" (BfArM), Bonn, Germany coronary vessels and peripheral blood vessels are the two largest areas of application for stent implants in Germany. Furthermore, vascular stent implants are used in the area of cerebral blood vessels. Clinical indications are arterial occlusive disease caused by fatty and calcium deposits as well as vascular aneurysms. Stent implants in the non-vascular system are mainly used in the upper and lower digestive tract and in the respiratory tract. The number of stent procedures is increasing in almost all medical specialties worldwide. Figure 1 shows the development of operation codes (OPS) of relevant medical specialities in Germany (2010 – 19) [MGJ+22].

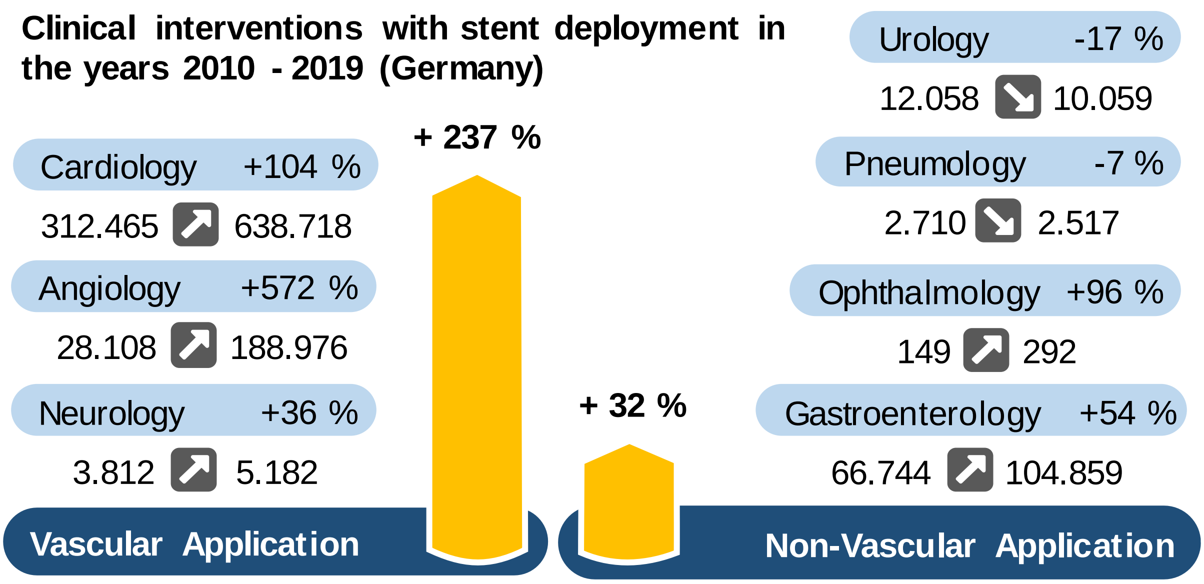

Figure 1: Stent implantations in Germany (2010 – 2019) [MGJ+22]

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Design and manufacturing processes of current stent implants differ depending on the area of application. Laser cutting and wire-based braiding have become the most popular manufacturing methods [MGJ+22]. Cut stent implants are mainly used in vascular vessels with small diameters. Examples are the coronary or cerebral vessels. In the area of larger vessel and organ diameters, such as peripheral blood vessels, and in non-vascular applications, wire-based stent implants are predominantly used due to the better material utilisation in production as well as a higher flexibility of the products. While the production of cut stent implants has already been automated, wire-based stent implants are mainly produced in manual steps due to the complexity of the structure-forming process. The increasing demand is contrasted by a production with a high proportion of manual work steps. This results in high costs due to wages, training, rejects and costly quality controls. According to German SMEs, the manual work steps account for 80 % of the manufacturing costs in the production. An estimation of the percentage composition of the sales price of a stent system with catheter and the manufacturing costs of a stent implant are given in Fig. 2. [MGJ+22]

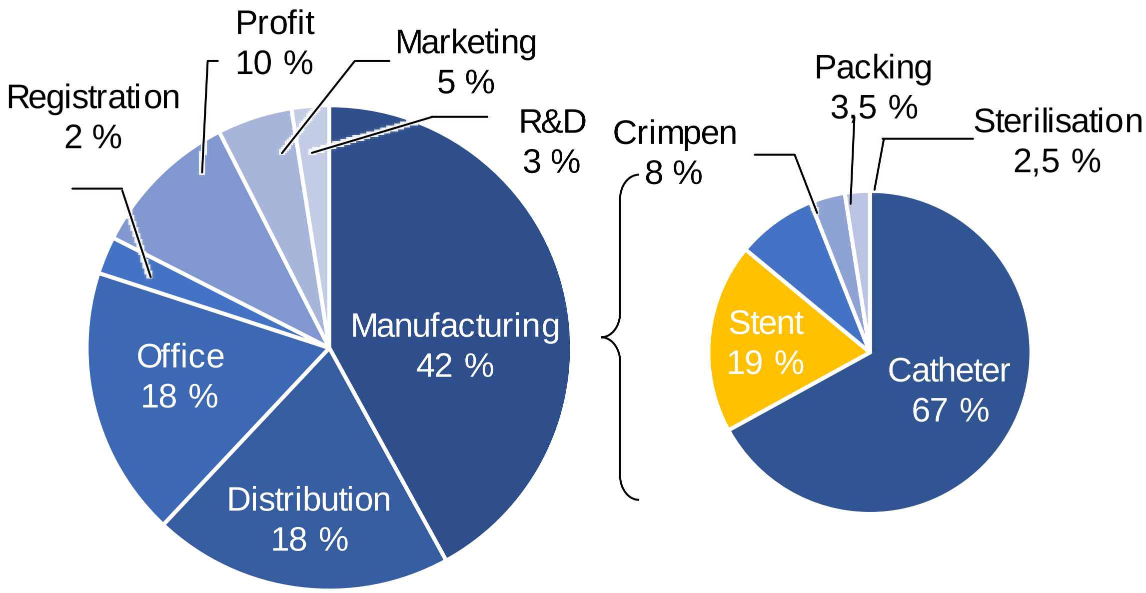

Figure 2: Estimation of the Composition of the sales price (left) and the manufacturing costs of a stent system (right) [Mer23]

As part of a research field at the Institute of Textile Technology at RWTH Aachen University (ITA), various automated approaches for the production of atraumatically braided stent implants were evaluated and two selected processes were implemented. The first approach, "automated single-thread braiding" (AEF), is the automation of the manual single-thread braiding process based on the state of the art. The second approach, "atraumatic multi-thread braiding" (AMF), consists of an extension of the conventional round braiding process through targeted manipulation of the wire deposit so that atraumatic round braids can be produced. The goals of the development work are the development and implementation of the automated manufacturing processes as well as the proof of technical suitability through mechanical validation of automatically manufactured, atraumatic stent implants (according to DIN EN ISO 25539-2) as well as the evaluation of economic efficiency based on manufacturing costs. [Mer23]

2. Automated single-thread braiding

Automatic single-thread braiding is being researched as part of the public KMU-innovativ project "AnaMag" (BMBF). The technical implementation of the braiding process is based on three central system components. A core system, which contains a braiding core for structure formation as well as kinematics for the rotation of the same. Two storage systems, which temporarily store the wire according to the first-in-first-out principle. As well as a positioning unit, which is responsible for the wire guidance in order to create the braided product (see Figure 3). [Mer23]

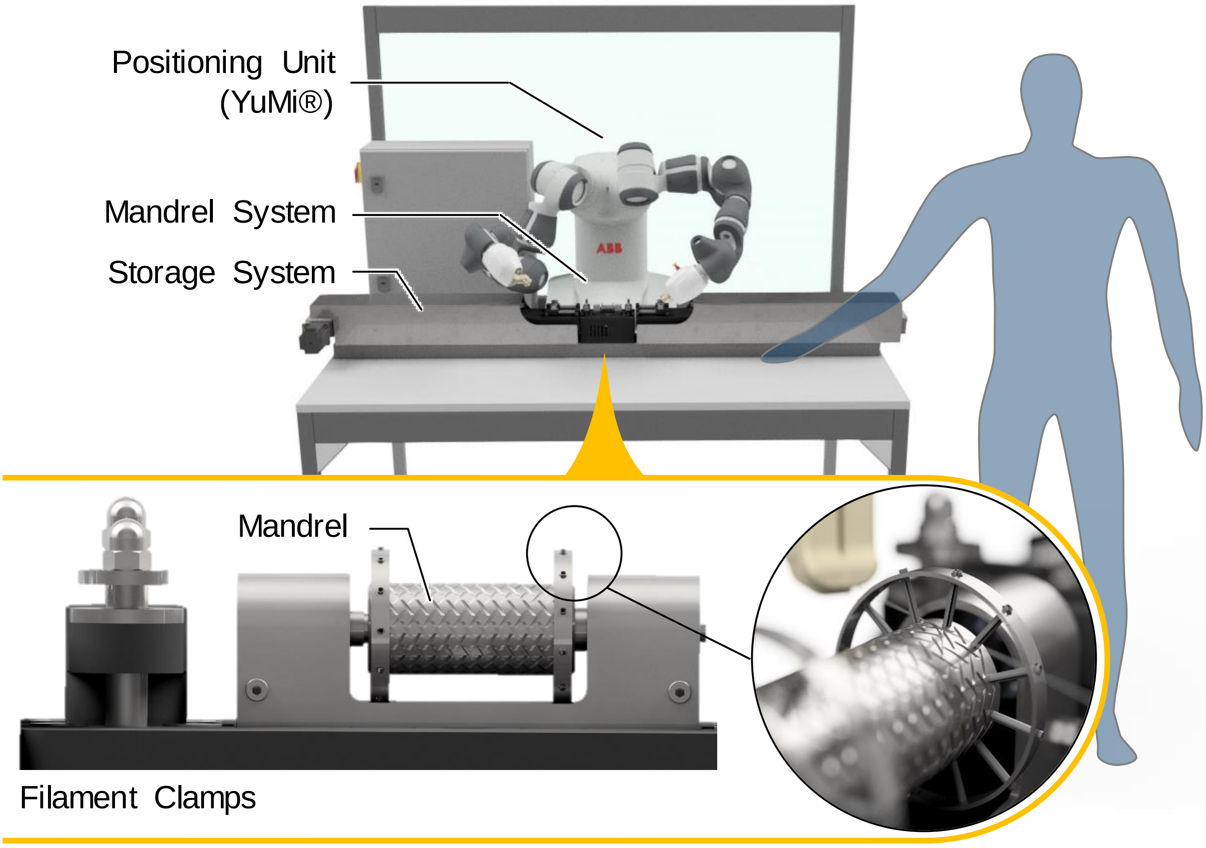

Figure 3: Automated single-thread braiding [Mer23]

The braiding process is implemented using the YuMi® - IRB 14000 collaborative robot (positioning unit). The other modules (storage system and core system) were developed and implemented within the project. Within the framework of a partially automated implementation, stent implants with atraumatic ends were successfully produced and validated (see Figure 6). [Mer23]

3. Atraumatic multi-thread braiding

The atraumatic multi-thread braiding process is based on the round braiding process. The development took place in the publicly funded ZIM project "StEnd" (AiF). Through a targeted manipulation of the wire deposit in s-curves, perforated braids were automatically generated, which result in atraumatic structures with appropriate fabrication and a joining step (Figure 4-6). [Mer23]

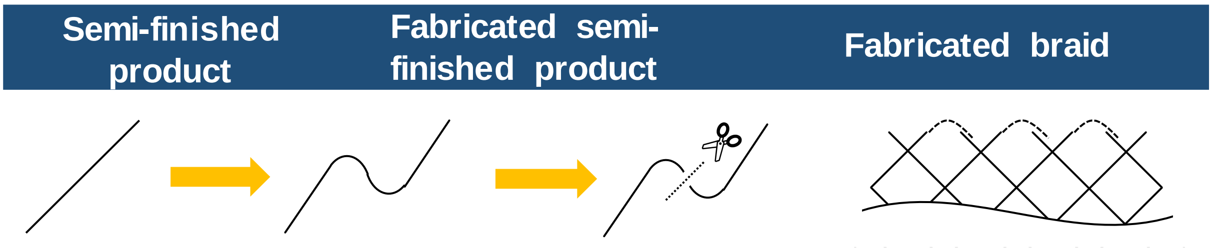

Figure 4: Basic principle of atraumatic assembly [Mer23]

A corresponding 3-axis manipulator for the automated control of wire deposition was developed and successfully validated using a circular braiding machine (Steeger HS80/48-VAE). The process has proven to be suitable for the production of atraumatic multithread stents (see Figure 6) and is currently being further developed within the framework of a follow-up project (ZIM project "BioStend"). [Mer23]

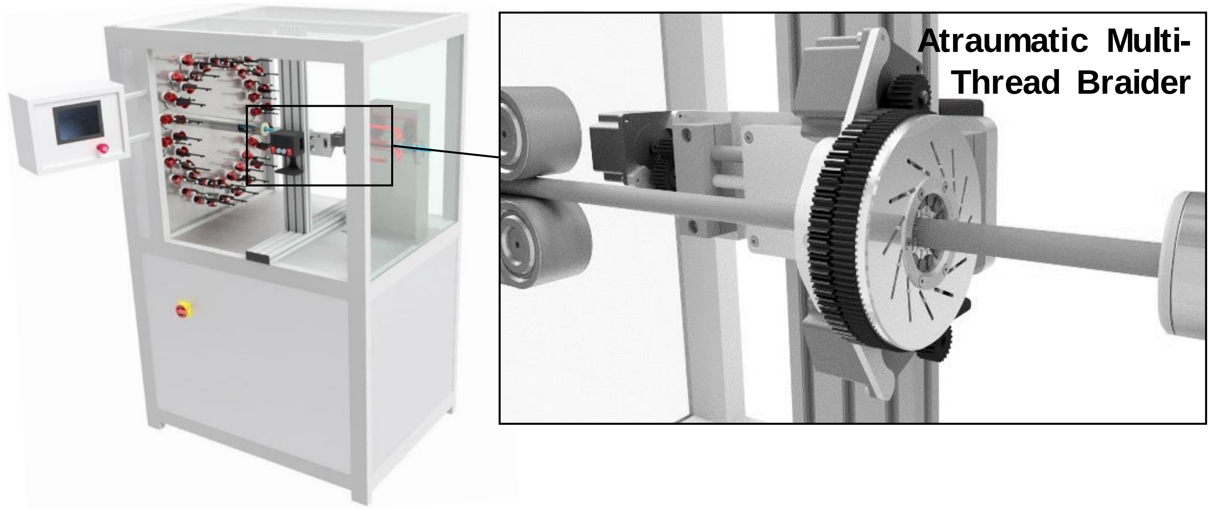

Figure 5: Atraumatic multi-thread braider within a Steeger HS80/48 [Mer23]

4. Evaluation

The mechanical validation of the implants of both methods was carried out according to DIN EN ISO 25539-2. The comparison of Radial Resistance Force (F_{RRF}) and Chronical Outward Force (F_{COF}) as a basic target value results in comparable mechanical properties to manually braided benchmark implants. With appropriate thermal treatment (e.g. in a salt bath or fluidised bed oven), comparable mechanical properties can be achieved with manually braided stents or commercial products (Figure 6). From a technical point of view, the manufacturing processes are therefore considered successful. [Mer23]

Medium: Air;	Temperature: 37 °C	Testing Speed: 20 mm/min
Nr. of Spec.: 3;	Cycles: 3;	DIN EN ISO 25539-2

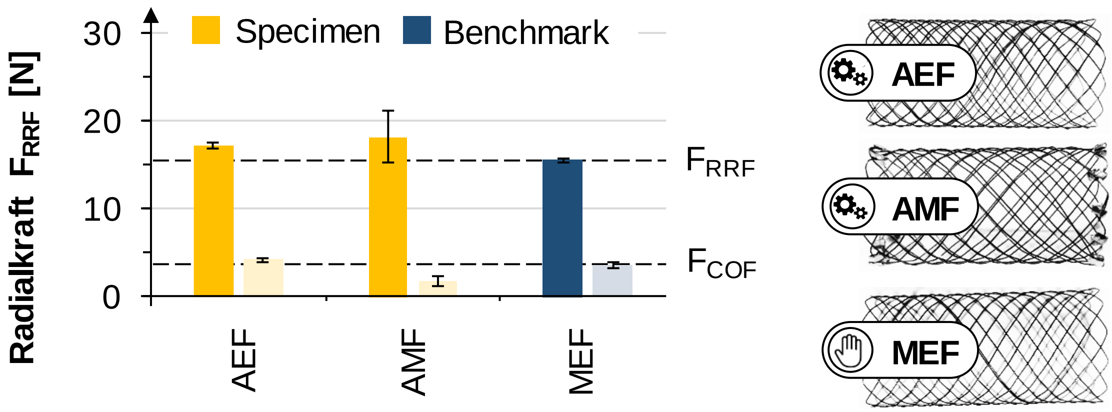

Figure 6: Mechanical characterisation of the stent implants [Mer23]

To evaluate the economic efficiency of the manufacturing processes, concepts of fully automated production lines were developed and process costs were determined on the basis of the machine and operating costs. The evaluation of the processes based on a subsequent manufacturing cost calculation shows that the manufacturing costs can be reduced by 70 - 73% compared to the respective manual procedures (Figure 7). Wage costs, set-up and manufacturing costs as well as material loss costs are identified as central cost drivers in the manual production of stent implants. Another relevant cost factor according to German SMEs is the costly quality assurance due to high reject rates in manual production of up to 20 %. A high proportion of the rejects is attributed to excessive tensile and bending stresses on the braided wire and the resulting cracking in the crowns of the stent implants as well as defective weld seams. These product defects are often only discovered after several process steps in the downstream and cause corresponding process costs. According to OEM manufacturers, each braided stent is unique and product characteristics and scrap rates are highly dependent on the skill of the individual employee. The costs due to familiarisation, training, rejects as well as costly quality control and documentation can be reduced by automating the structure formation. It is therefore assumed that the economic potential of the automated processes is higher than the values determined. [Mer23]

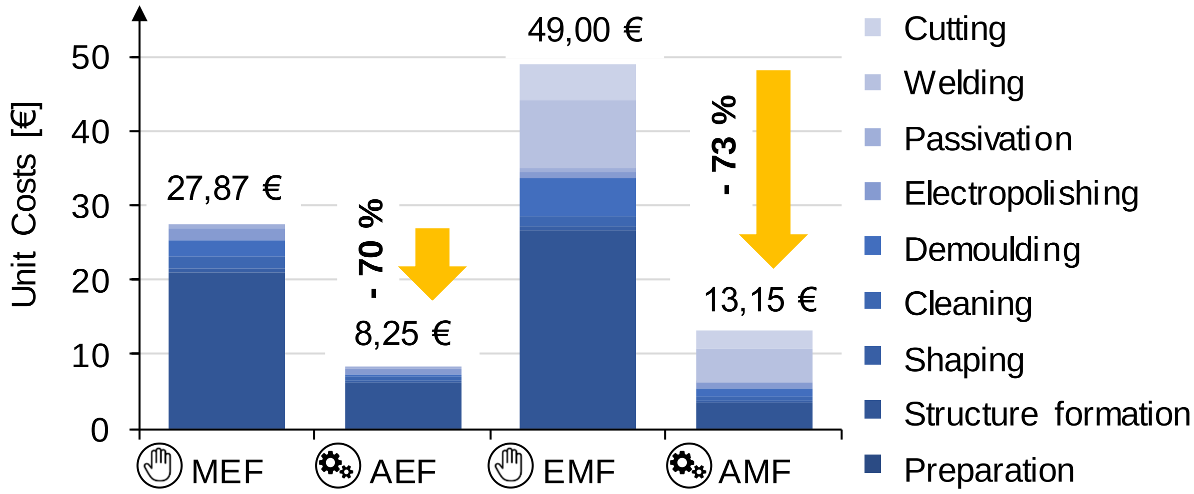

Figure 7: Unit cost comparison of the production chains [Mer23]

5. Conclusion

The worldwide demand for stent implants is increasing. Wire-based stent implants are suitable for the rapidly growing field of medium to large lumen applications due to economic and technical aspects. Key advantages are about 20 times lower material costs compared to cut implants as well as the high flexibility of the implants. The increasing demand is contrasted by predominantly manual manufacturing processes, which account for up to 80 % of the manufacturing costs. In addition, distributors and OEM manufacturers of stent implants are facing major economic challenges, such as the increasing regulation of the market, e.g. through the MDR EU 2017/745 regulation for medical devices. In addition, price pressure is increasing due to growing competition, a stronger negotiating position of customers and cost pressure from healthcare systems and health insurance companies. German implant manufacturers in particular are therefore avoiding the low-price mass market and are striving for a high degree of specialisation and manufacturing quality as well as customer-oriented production with the "Made in Germany" seal of medium series sizes or individual implants. A high degree of automation for cost-effective, customer-oriented production is desirable. Within the research field "Atraumatic Stent Implants" at the Institut für Textiltechnik der RWTH Aachen, two technical approaches have been successfully developed and validated to enable cost-effective and local production. Based on a technical and economic evaluation, it was shown that both solution approaches are fundamentally suitable for the cost-effective production of atraumatic stent implants. An assessment of the technology attractiveness based on OR codes and ICD classification, patent applications and publications, available products and product prices makes it clear that automated single-thread braiding in particular has a high potential in application (Figure 8). [Mer23]

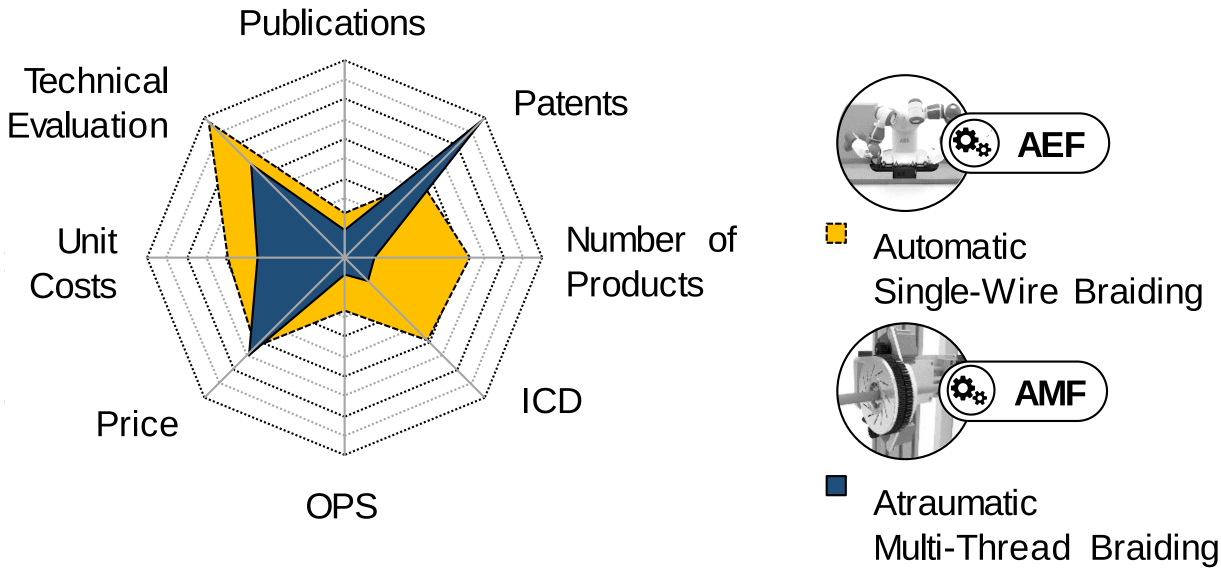

Figure 8: Classification of technology attractiveness [Mer23]

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6. Sources

[MGJ+22] Merkord, F.; Grimm, Y.; Jaworek, F.; Gries, T.; Overview on the Current Global Market of Stent Implants – Market Research 2020 – 21; Shaker Verlag, Düren; April 2022

[Mer23] Merkord, F.; Evaluierung automatisierter Verfahren zur Herstellung drahtbasiert geflochtener Stentimplantate, Shaker Verlag, Düren; März 2023