Kaunas University of Technology
Faculty of Mechanical Engineering and Design

Structured Problem Solving Methods Application for Modernization of PVC Tubing Assembly Process

Master's Final Degree Project

Gertrūda Nariuševičiūtė
Project author

Lect. Darius Pauliukaitis
Supervisor

Kaunas, 2023

Kaunas University of Technology
Faculty of Mechanical Engineering and Design

Structured Problem Solving Methods Application for Modernization of PVC Tubing Assembly Process

Master's Final Degree Project

Industrial Engineering and Management (6211EX018)

Gertrūda Nariuševičiūtė
Project author

Lect. Darius Pauliukaitis
Supervisor

Lect. Laura Gegeckienė
Reviewer

Kaunas, 2023

Kaunas University of Technology

Faculty of Mechanical Engineering and Design

Gertrūda Nariuševičiūtė

Structured Problem Solving Methods Application for Modernization of PVC Tubing Assembly Process

Declaration of Academic Integrity

I confirm the following:

1. I have prepared the final degree project independently and honestly without any violations of the copyrights or other rights of others, following the provisions of the Law on Copyrights and Related Rights of the Republic of Lithuania, the Regulations on the Management and Transfer of Intellectual Property of Kaunas University of Technology (hereinafter – University) and the ethical requirements stipulated by the Code of Academic Ethics of the University;

2. All the data and research results provided in the final degree project are correct and obtained legally; none of the parts of this project are plagiarised from any printed or electronic sources; all the quotations and references provided in the text of the final degree project are indicated in the list of references;

3. I have not paid anyone any monetary funds for the final degree project or the parts thereof unless required by the law;

4. I understand that in the case of any discovery of the fact of dishonesty or violation of any rights of others, the academic penalties will be imposed on me under the procedure applied at the University; I will be expelled from the University and my final degree project can be submitted to the Office of the Ombudsperson for Academic Ethics and Procedures in the examination of a possible violation of academic ethics.

Gertrūda Nariuševičiūtė

Confirmed electronically

Kaunas University of Technology

Faculty of Mechanical Engineering and Design

Task of the Master's Final Degree Project

Given to the student – Gertrūda Nariuševičiūtė

1. Title of the Project

Structured Problem Solving Methods Application for Modernization of PVC Tubing Assembly Process

(In English)

Struktūrizuoto problemų sprendimo metodų panaudojimas polivinilchlorido vamzdelių sujungimo procesui modernizuoti

(In Lithuanian)

2. Aim and Tasks of the Project

Aim: to apply structured problem solving methods for modernization of PVC tubing assembly process.

Tasks:

1. to compare at least 2 ways of tubing assembly process;
2. to indicate at least 2 problems of tubing assembly process;
3. to provide alternative solution for connecting tubes;
4. to evaluate economical value for proposed alternative solution.

3. Main Requirements and Conditions

Polyvinyl Chloride;
Structured Problem Solving Methods;
Computer Aided Design program "Solidworks"

4. Additional Requirements for the Project, Report and its Annexes

Not applicable

Project author	Gertrūda Nariuševičiūtė		2023 03 03
	(Name, Surname)	*(Signature)*	*(Date)*
Supervisor	Darius Pauliukaitis		2023 03 03
	(Name, Surname)	*(Signature)*	*(Date)*
Head of study field programs	Regita Bendikienė		2023 03 03
	(Name, Surname)	*(Signature)*	*(Date)*

Nariuševičiūtė Gertrūda. Structured Problem Solving Methods Application for Modernization of PVC Tubing Assembly Process. Master's Final Degree Project, supervisor lect. Darius Pauliukaitis; Faculty of Mechanical Engineering and Design, Kaunas University of Technology.

Study field and area (study field group): Production and Manufacturing Engineering (E10), Engineering Sciences (E).

Keywords: structured problem solving; A3 report; DMAIC; tubing; rotary friction welding; snap-fit assembly; PVC.

Kaunas, 2023. 62 p.

Summary

Structured problem-solving methods were applied for modernizing polyvinylchloride tubing assembly process in company "X", that manufactures and supplies medical devices. This final degree project aims to apply structured problem-solving techniques to modernize the PVC tubing process. In the first part the significance of usage of structured problem-solving methods in variety of fields, such as manufacturing, medical, education, environmental and business management, was explained. Moreover, the benefits and drawbacks of several methods for joining components, including solvent welding, adhesive bonding, welding, and mechanical connections were discussed in the second project part. What is more, as project experimental part, the A3 report, based on the DMAIC methodology, was applied to solve the problem of the rotary friction welding process – a narrowed welding seam connecting the catheter and the urine collection bag. The results of the study showed the dependence of the quality of the welding seam on the wear of the mechanical parts and their installation, the quality of the raw materials and the hand-folding urine collection bags. The six-week data showed that the implemented actions brought positive results: the team managed to reduce the number of defects within the target and documented the actions that allowed to control the quality of the manufactured products. For a long-term solution, it was decided to change the connection between the catheter and the urine collection bag to a snap-fit connection. To do this, a new design of the raw material was created, the equipment mechanical parts and software program were updated. The final degree project evaluated the economic benefit of the A3 study and the new tubing connection.

Nariuševičiūtė Gertrūda. Struktūrizuoto problemų sprendimo metodų panaudojimas povinilchlorido vamzdelių sujungimo procesui modernizuoti. Magistro baigiamasis projektas, vadovas lekt. Darius Pauliukaitis; Kauno technologijos universitetas, Mechanikos inžinerijos ir dizaino fakultetas.

Studijų kryptis ir sritis (studijų krypčių grupė): Gamybos inžinerija (E10), Inžinerijos mokslai (E).

Reikšminiai žodžiai: struktūrizuotas problemų sprendimas; A3 ataskaita; DMAIC, vamzdelių sujungimas; rotacinis frikcinis suvirinimas; snap-fit jungtis; PVC.

Kaunas, 2023. 62 p.

Santrauka

Medicinos prietaisus gaminančioje ir tiekiančioje įmonėje „X“ polivinilchlorido vamzdelių sujungimo procesui modernizuoti pritaikyti struktūrizuoti problemų sprendimo metodai. Šiuo baigiamuoju projektu siekiama pritaikyti struktūrizuotus problemų sprendimų būdus polivinilchlorido vamzdelių sujungimo procesui modernizuoti. Pirmoje projekto dalyje nurodyta struktūrizuotų problemų sprendimo būdų panaudojimo svarba įvairiose srityse, pavyzdžiui, gamyboje, medicinos pramonėje, švietimo, aplinkosaugos ir verslo valdymo. Kitoje projekte dalyje apžvelgti įvairūs komponentų jungimo būdai: suvirinimas, klijavimas, suvirinimas tirpikliu ir mechaninės jungtys, jų privalumai ir trūkumai. Baigiamojo projekto tyrimo dalyje pritaikytas A3 ataskaitos įrankis, paremtas DMAIC metodika, spręsti rotacinio frikcinio suvirinimo proceso problemai – susiaurėjusi suvirinimo siūlė, jungianti kateterį ir šlapimo surinkimo maišelį. Tyrimo rezultatai parodė suvirinimo siūlės kokybės priklausomybę nuo įrengimo mechaninių dalių išsidėvėjimo ir jų instaliavimo, žaliavų kokybės ir rankomis lankstomų šlapimo surinkimo maišelių. Šešių savaičių duomenys parodė, jog įgyvendinti veiksmai atnešė teigiamų rezultatų: komandai pavyko sumažinti defektų skaičių neviršijant tikslo ir uždokumentuoti veiksmus, leidžiančius kontroliuoti pagamintų produktų kokybę. Ilgalaikiam sprendimui nuspręsta pakeisti kateterio ir šlapimo surinkimo maišelio sujungimą į snap-fit jungtį. Tam padaryti buvo sukurtas naujas žaliavos dizainas, atnaujinta mechaninės įrengimo dalys ir įrengimo programinė įranga. Baigiamajame projekte įvertinta A3 tyrimo ir naujo vamzdelių sujungimo ekonominė nauda.

Table of Contents

List of Figures

List of Tables

Introduction

In order to ensure a more effective problem-solving process, businesses are now attempting to apply a number of different approaches. Together with using various techniques, teamwork should be seen as a crucial component of a problem-solving process. Different departments' contributions, attitudes, and methods can help solve issues more quickly, save time, and produce better results.

Nowadays, the usage of structured problem-solving methods are increasing in international and competitive companies. It is said that such approach allows to acknowledge challenges and turn them into possibilities. Concept of structured problem solving is evolving in various fields starting from production, medical industries to education and fashion area. Improvement can be seen through developed different methods and tools, which are used for analysis of various challenges. This means that problem solving is inevitable in any business area. In general, three types of methods are indicated: the creative path of design thinking. hypothesis-driven or issue-driven problem solving [1]. However, it takes additional skills and knowledge to master challenges successfully. For years methods for finding solutions have been developed and the process is still continuously improving.

What is more, manufacturing is continually evolving in the modern day, from concept development to procedures and technologies available for the production of goods. Manufacturing has traditionally been defined as the process of transforming raw materials into finished products that are then sold on the market. Instead, production is now viewed as an "integrated concept" at all levels, from the machinery and control systems to the broader business operations. Even with all improvements and updates, plenty of difficulties have been faced in shopfloor. Challenges can be equipment related (machine efficiency, defect rate, maintenance), material related (design requirements, material choices), supplier related (legal agreements, communication strategies) and many other. This shows that efficient and useful tips are required on finding solutions for the mentioned problems.

Thus, this paper considers a production process in medical industry and its key challenges. This paper discusses various ways of polyvinyl chloride tubing assembly during a mass production line. Tubing assembly is a main process for connecting a catheter and an urine collection bag. Therefore, finding possibilities for improvement to constant challenges it is highly beneficial for a company ‘X’, while using structured problem-solving methods. Analysing and modernizing a tubing assembly process provide positive results by increasing equipment efficiency, diminishing expenses of produced parts in unaccepted quality and providing an alternative product to customers.

Aim: to apply structured problem solving methods for modernization of PVC tubing assembly process.
Tasks:
1. to compare at least 2 ways of tubing assembly process;
2. to indicate at least 2 problems of tubing assembly process;
3. to provide alternative solution for connecting tubes;
4. to evaluate economical value for proposed alternative solution.

Hypothesis: Application of a structured problem solving method for the modernization of PVC tubing assembly process enables a solution to be found that increases manufacturing output while reducing defect rate and manufacturing costs.

1. Structured Problem Solving Importance

For many years, not only industrial engineers, but also medical workers, political and economic figures, educators and business managers, solve problems all around the world. Many of them indicate that non-structural problem tackle is a roadblock to effective workflow. Therefore, in order for the organization to keep progressing, more recent and useful troubleshooting techniques must be used.

Nevertheless, modern methodologies are based on efficiency, waste reduction and continuous improvement, one of the examples – Lean methodology. Structured problem solving is one of the Lean principles, where high priority is taken to concrete situation analysis and providing data driven developments. Moreover, numerous of methods have been developed to adapt to high variety of fields. Generally, problem solving methods can be grouped into:

- Cause and effect analysis,
- Statistical analysis,
- Risk based analysis.

However, combining several techniques into one bigger analysis defines a disciplined problem-solving approach. Great method defines understanding of the situation, data collection and processing, risk management and formulation of conclusions.

To begin with, a commonly applied method of A3 report is widely used in manufacturing industry. The main idea of A3 approach that thorough analysis and well-structured resolution is presented on a single page in A3 format. Additionally, research of the use of the A3 tool by a manufacturer of motorbikes at the Manaus Industrial Pole is discussed. Even if casting, machining, stamping, aluminium, metal, and plastic dying, welding, engine, and chasses assembly are all production processes, machining processing is the most important one. Due to the fact that sales have increased dramatically in 2020, there is widespread concern that the regular motorcycle manufacturing capacity cannot be met. The issue was thus reduced to the primary issue of an excessively long setup time for the crankcase line. As a result of the process improvement that was implemented, the setup time for the machines was decreased by around 70% as a result of following the steps of the A3 technique (Fig. 1) [2]. In order to fulfill the strategic plans, it may be argued that disciplined problem solving assisted a corporation in identifying valuable and non-valuable tasks of a particular process and reduced needless time.

Another reason why structured problem-solving tools are functional nowadays that it assists businesses in avoiding escalating expenses by eliminating scrap. For instance, lean manufacturing is used by at least two thirds of firms USA based and about half of UK companies. It indicates that a large number of workers are implementing procedures for continuous improvement and fundamentally altering daily operations. A study was done in a plastic injection company in the Indonesian region. One of the labelling machinery was failing and rejecting products because the body of the bottle body was dusty. As a result, this research stopped the organization from performing plurality reworks [3].

Fig. 1. Comparison of carcass line process timing before and after improvements [2]

The employment of problem-solving approaches in the medical industry is another crucial factor. This is due to the fact that in the USA, medical errors were one of the top 10 main causes of death in 1999. 110 errors were discovered in the histology laboratory during the analysis. Mistakes include incorrect labelling, grammatical issues, improper archiving, and many others. Following the study, countermeasures were implemented, including lean management, hiring more people who would assume archiving responsibilities, and improving visibility in the archive room [4]. Despite of this, in University of Pennsylvania Perelman School of Medicine it is crucial to gain skills quality improvement for healthcare professionals in 2021. This also include application of structured problem-solving method – A3 report [5].

What is more, in order to make emergency rooms more efficient, Lean approach was used. A study shows that applying DMAIC principle duration of patients stay was reduced in one third, as well satisfactory level risen four times. Method consists of five stages, where project scope was defined, current situation was analysed, measurements system was validated, five Why analysis conducted improvements were implemented and controlled [6]. Moreover, wide variety of research methods were chosen to resolve patients overcrowding in emergency room, in Saudi Arabia (Fig. 2). This indicated that issue was being solved through three different points of view: process, employees and customers. Understanding the process, tacking challenges in structural manner and focusing on patients helped to identify main causes of overcrowding (layout design, employee shortage, unorganized data recording…) and minimize waste in quality management, emergency department facilities, administration and others [7].

Furthermore, disciplined problem solving ought to be promoted from an early age and included in educational programs. For instance, students at Massachusetts Institute of Technology (MIT) studying industrial engineering analyse case studies using A3 reports [8]. Another study demonstrates that students typically approach problems in an unstructured, memory-based, or unclear manner. When testing direct current electricity, pupils who applied a scientific approach to problem solving displayed higher outcomes [9]. Thus, even before joining the employment market, critical thinking and organized problem-solving skills are being encouraged.

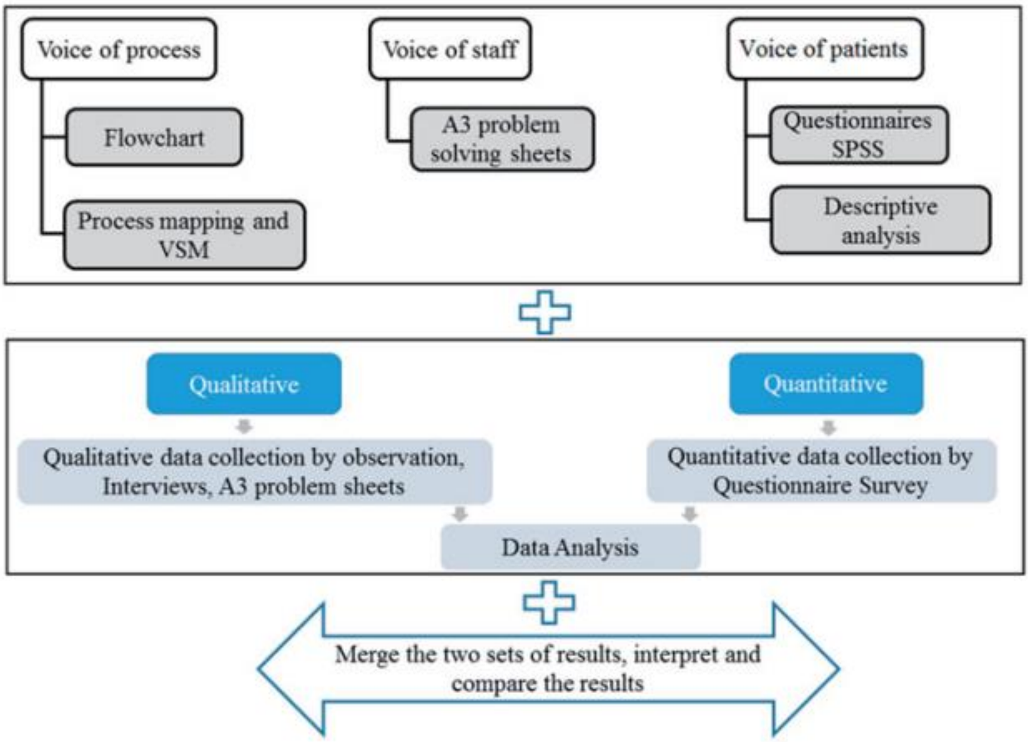


Fig. 2. Research methods for optimizing patients flow in emergency room [7]

In addition, publications are now available that highlight the presence of the previously stated method's application, without minimizing how important the sustainability and environmental topics are. It is urged that more people adopt green transportation because it reduces greenhouse gas emissions. However, implementing the revolution in sustainable transportation is not so simple; as a result, structured problem-solving techniques were employed [10]. Moreover, a cause-and-effect study was performed to look at the underlying factors of fire disasters in Nigeria. The study revealed several key causes, including wiring issues, improper chemical handling, arson, and drug addiction. As a result, the Ishikawa diagram assisted in reaching conclusions about things like careful supervision in laboratory classes, eliminating overloaded electrical outlets, and isolating school grounds from outsiders [11].

Finally, examples of structured problem-solving approaches are found in business management and political areas. In Mexico, senior managers of automotive industry faced challenges in developing consensus upon opposing viewpoints and deciding business priorities, while contrasting management philosophies. As a result, Hoshin Kanri method, which incorporates an A3 report was employed to give continuous improvement initiatives more weight and reduce the likelihood of managerial conflicts throughout strategic planning process [12]. Other point of view was introduced by the study of trade war between United States of America and China. Rootcause investigation was conducted to understand main reasons of this war and conclusions were made to warn other impacted countries about negative consequences [13].

When all factors are taken into account, applying systematic methods is seen as an appropriate strategy to find solutions to issues across variety of different fields. It is advisable to approach problems in a scientific way not just in the professional domain but also to start encouraging children to develop their logical abilities.

1.1. Summary of Structured Problem-Solving Significance

Structured problem solving is an important part of the Lean methodology, which is based on efficiency, waste reduction and continuous improvement. It involves combining several techniques into one bigger analysis, such as cause and effect analysis, statistical analysis, risk-based analysis, and risk management. A3 report is widely used in manufacturing industry, with the main idea that thorough analysis and well-structured resolution is presented on a single page in A3 format. This technique was used to reduce setup time for the crankcase line by around 70%. To fulfil strategic plans, structured problem solving assisted a corporation in identifying valuable and non-valuable tasks and reduced needless time. Structured problem-solving tools are essential for businesses to avoid escalating expenses by eliminating scrap. Lean manufacturing is used by at least two thirds of firms USA based and about half of UK companies. In the medical industry, medical errors were one of the top 10 main causes of death in 1999. Lean management, hiring more people, and improving visibility in the archive room were implemented to make emergency rooms more efficient. In Saudi Arabia, a variety of research methods were chosen to resolve patients overcrowding in emergency rooms, focusing on process, employees, and customers. Disciplined problem solving should be promoted from an early age and included in educational programs. Examples of structured problem-solving approaches are found in business management and political areas, such as the Hoshin Kanri method and the trade war between US of America and China. It is advisable to approach problems in a scientific way not just in the professional domain, but also to encourage children to develop their logical abilities.

2. Assembly Methods and Challenges

Combining two or more parts has proven to be a difficult procedure over the years. Similar issues, such as material compatibility, surface preparation, and weld quality, arise during the assembly of both metal and plastic components [14]. Additionally, there are new difficulties for metallic components, such as corrosion and thermal expansion [15]. But compared to joining metal components, plastic parts typically cost more, pollute the environment, require greater safety measures, and have specially designed joints [16]. Various literature sources list different types of joining processes, however, main assembly methods can be stated as mechanical, welding, adhesive bonding and solvent welding [17] (Fig. 3).

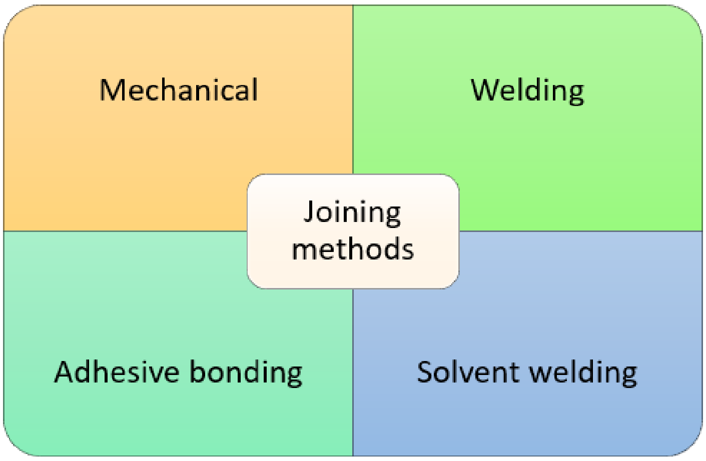


Fig. 3. Joining methods

Describing each method:

- Mechanical assembly is a process of joining or connecting two or more parts of a mechanical system to form a complete and functional unit. Additional parts, such as nuts, bolts, screws, washers, bearings, gears, shafts, and other mechanical parts, must be used in this construction (Fig. 4). Additional tooling is selected in accordance with the design's technical specifications, the structure's overall weight, its ability to endure loads, and other factors. It takes a high degree of precision, accuracy, and attention to detail to use this method, which is widely used, to ensure that the finished product meets the necessary specifications. In order to prevent human errors, contemporary methods are used, such as augmented reality [18].

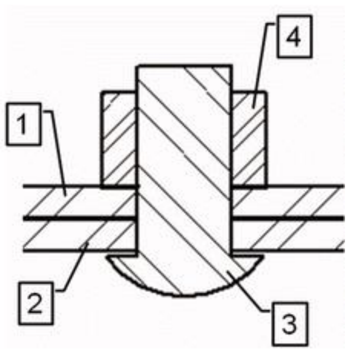


Fig. 4. Example of mechanical assembly, where 1 – first part, 2 – second part, 3 – bolt, 4 – nut [19]

- Using an adhesive substance to join two or more objects together is known as adhesive bonding. Natural or manufactured adhesives are available in a variety of forms, including liquids, pastes, films, and tapes. The two materials are pressed together to create a bond with the primary concept being that adhesive is first applied to the surface of the material to be bonded (Fig. 5). A strong bond that can endure tension and pressure is formed when the adhesive seeps into the pores and crevices of the material's surface [20].

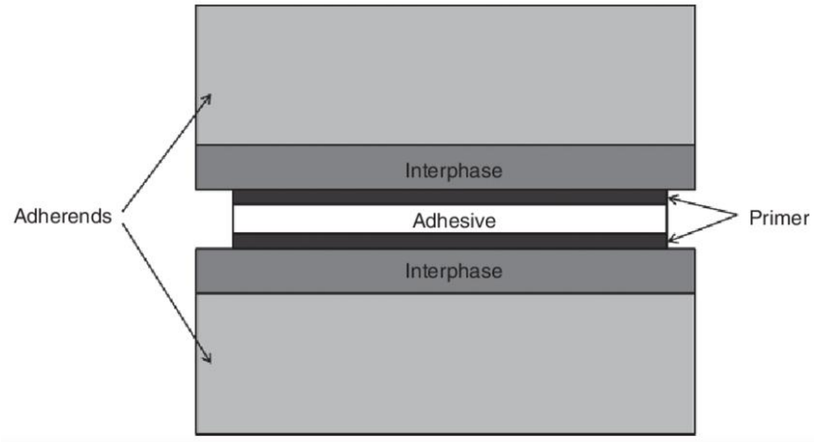


Fig. 5. Illustration of an adhesively linked joint [21]

- Using a chemical solvent, solvent welding is a method of joining plastic components, typically pipes (Fig. 6). When the parts are pushed together, the melted layers fuse together as the solvent dissolves the plastic's surface, forming a melted layer that results in a solid bond [22].

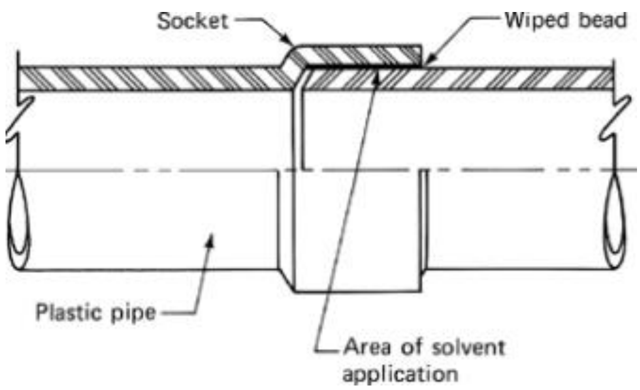


Fig. 6. Tubing in solvent welding [23]

- A join is formed as two or more pieces cool during the welding process, which involves the use of heat, pressure, or both. The most common materials for welding are metals and thermoplastics, but timber can also be used. A weldment is the term used to describe the finished welded connection. In addition, a wide range of welding techniques are recommended in this day and age, including welding cylinders and cubical structures [24].

The benefits and drawbacks of the different techniques can be compared in great detail. One of the evaluation criteria which could be taken into account the capacity to repeatedly assemble parts. It is possible that some mechanical systems will become detached. For instance, if parts are connected by threaded fasteners, disassembling them is not a difficult task (bolts, screws). However, it is important to consider tooling depreciation. Thread tends to dull when reassembly takes place frequently, but it is cheap to buy additional fasteners or repair the damage [25]. Snap fit or press fit joints are another reversible example and a great choice for rapid assembly [26]. However, some mechanical joining techniques are unable to be reconnected because the components are permanently joined. Due to their relative simplicity and low cost as a means of joining components, rivets are widely used for these purposes [27].

On the contrary, other joining techniques are intended to be everlasting. For instance, it is technically feasible to reattach joint parts during adhesive bonding, but it would damage the surface of the components. Thus, precisely for the mentioned joining method, the preparation and treatment of the component surface is one of the main crucial aspects for the well bonding quality [28]. Considering welding process, the connection is made by joining materials into one piece and for this reason it takes additional efforts to break it. Moreover, to break welded components, additional manufacturing processes, for example, drilling, grinding, cutting, or heating, have to be considered [29]. After reattaching the weldment, surfaces have to be prepared and welding process must be repeated. In some circumstances, components can get broken, demonstrating that welded connections are hardly reversible.

What is more, the majority of latest research in assembly science analyse and contrast mechanical connections and adhesive bonding primarily. Because weight management is essential in aerodynamics, the aerospace industry is the greatest illustration of how adhesive bonds are used [30]. In addition, study demonstrates that adhesive joints are widely used in automotive business in order to lower fuel consumption [31]. The main reason for this is that mechanically bonded structures include many fasteners, which increase overall construction weight, and adhesive materials weight relatively lower. Nevertheless, two assembly methods have been combined into one, which is hybrid bonding fastening. Better static strength and reduced number of fasteners were demonstrated in recent experiments [32].

Besides great results of adhesive bonding, some researchers stretched negative feedbacks. For instance, such joints are highly dependence on environmental factors (moisture absorption, temperature, joining process, adhesive type, treatment parameters) [30]. Another downside of adhesive that various surface treatments must be used. This is needed because rough surface has many grooves, which means that adhesive paste or glue would no bet equally spread (Fig. 7). Therefore, it can lower the strength of the bond.

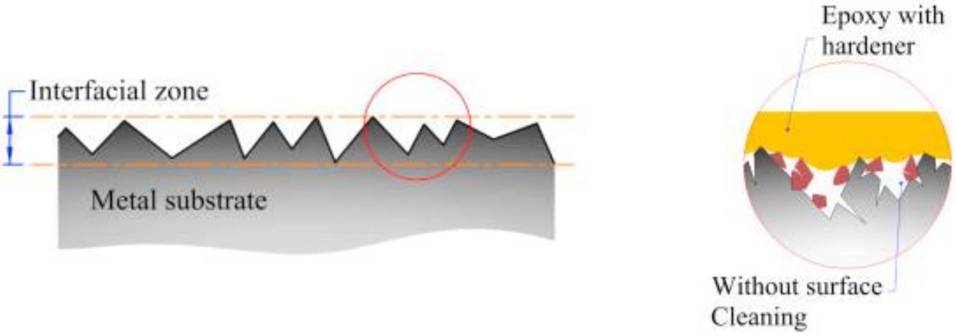


Fig. 7. Example of adhesive bonding without surface treatment [33]

Such procedures include:

- Plasma treatment, where electrically charged gas is used to alter characteristics of the surface of a material, placed in between electrodes [34].
- UV treatment is the exposing of a material's surface to ultraviolet rays in order to increase the bondability of polymers [35].
- Mechanical treatment, for instance, abrasion, which relieves the treated surface's residual tensions and radical formation [36].

Nevertheless, choices of surface treatments are highly dependent on various features of materials.

In conclusion, there are benefits and drawbacks to each joining technique, and the choice of technique relies on a number of variables, such as the materials being joined, the joint's strength requirements, and the application in consideration. While welding creates a permanent bond but calls for particular tools and experience, mechanical joining is robust and lasting but may need special instruments. While solvent welding can create a strong link for thermoplastics but necessitates cautious handling, adhesive bonding is adaptable and can bind disparate materials but may be impacted by environmental conditions.

2.1. Welding Types and Concerns

A procedure called welding involves melting and fusing two or more metal components together to form a single piece. There are numerous varieties of welding, each with benefits as well as disadvantages of their own. Arc welding, gas welding, friction welding, resistance welding, and thermit welding are a few of the most popular kinds of welding (Fig. 8).

While welding is a useful method for attaching metal components, it also raises a number of issues. Safety is one of the primary issues. Intense heat and light are produced during welding, and if the area is not properly ventilated, the fumes and gases that are released throughout the process can be harmful to the welder's health [37]. Quality control is still another issue. To make sure that they are free of flaws like fractures, porosity, and incomplete penetration, welds must be inspected. In order to ensure compatibility and the appropriate strength and longevity of the welds, the materials being welded must also be carefully chosen [38].

In conclusion, welding is a useful procedure for combining metal pieces, but it necessitates careful thought about the sort of welding process to be utilized as well as attention to safety and quality control considerations.

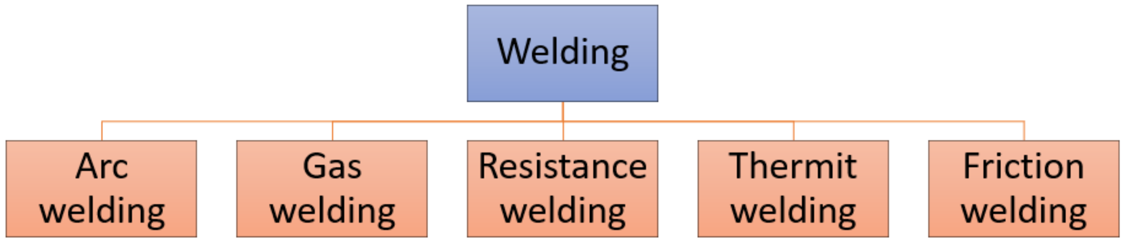


Fig. 8. Various types of welding processes

2.1.1. Friction Welding (FRW)

Nowadays in the solid state welding techniques known as friction welding, where two metal components are rubbed against one another until they obtain a plastic state, at which they are forged together. This method is economical and environmentally friendly approach to join metal pieces since it produces a strong long-lasting weld without the addition of flux or filler metal [39]. Numerous types of FRW are indicated, including rotary, linear, rotary friction, orbital and more innovative ones as vibration, explosive or ultrasonic welding (Fig. 9).

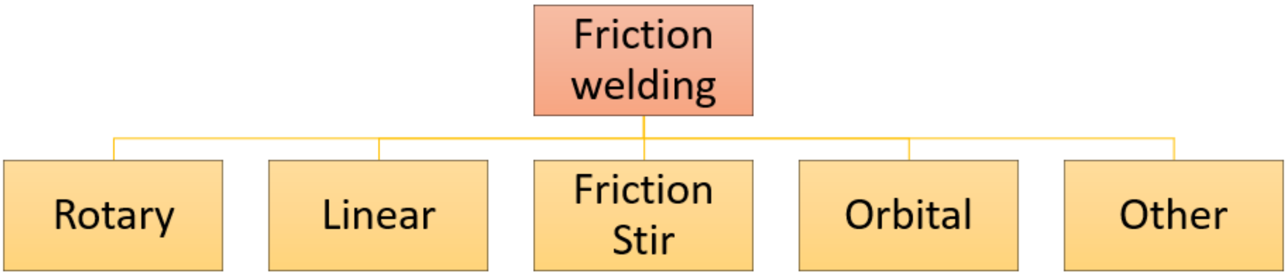


Fig. 9. Friction welding categories

During rotary friction welding the two cylindrical parts are brought into contact under pressure and rotated against each other at a controlled speed (Fig. 10). As a result, heat is produced through friction, melting the component surfaces and resulting in a plastic state. The plasticized material is extruded out from between the rotating pieces while they continue to rotate, leaving a flash that must be eliminated when the welding is accomplished. What is more, rotational speed, the number of revolutions, pressure, and duration are the main factors governing the process, providing repeatable and dependable output [40].

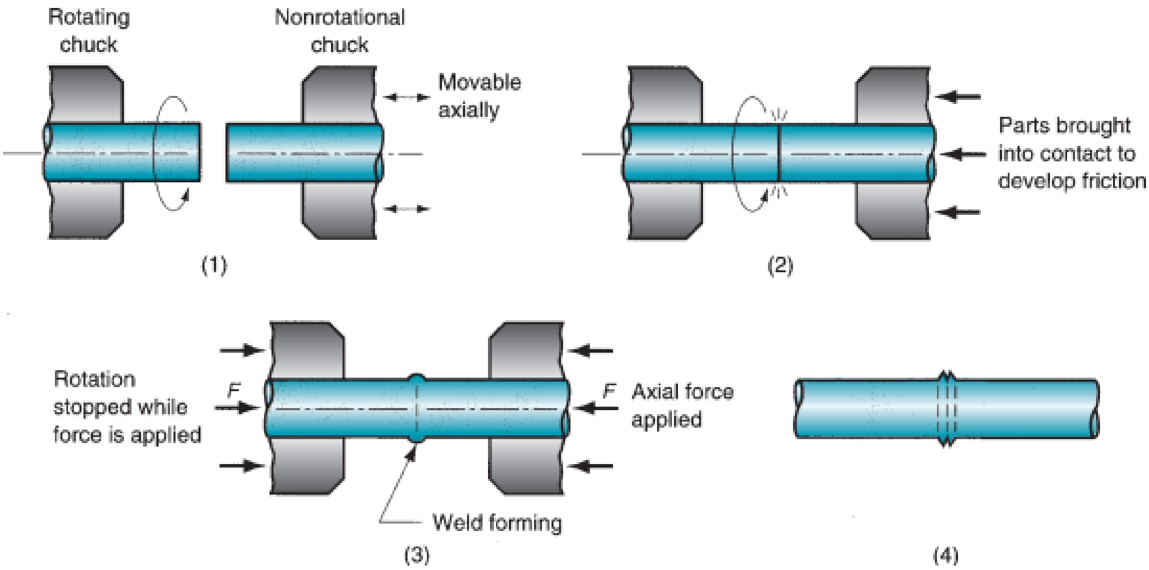


Fig. 10. Visualization of Rotary Friction Welding example, where 1 – rotating part, 2 – parts brought into contact, 3 – axial force applied and rotation is stopped, 4 – weld result [41]

The graph (Fig. 11) illustrates welding parameters dependency on time, when rotary friction welding is completed. Generally, three process phases are indicated: friction, braking and forging.

- During friction phase the rotational speed is the highest and constant, according to the specific material it can vary between 200 and 14000 revolutions per minute. Friction force remain constant and minimum, and torque firstly slightly increases and then remain steady. Moreover, an upset, as excess material, forms slowly, while components are in contact.
- Then braking phase is the shortest one, when spinning speed gradually decreases to zero and torque reaches its peak. During this time the temperature of the material surfaces in contact is the highest and the size of flash grows because the applied force is increased.
- Lastly, forging phase slightly interfere with the braking phase, but it last longer. This is the phase, where both speed and torques are equal to zero value, but highest axial force is applied. Duration of forging phase is crucial to ensure the strength of the bond. Whether rotational motion is stopped abruptly before the weld has solidified, it can cause the weld to be weak or incomplete [42].

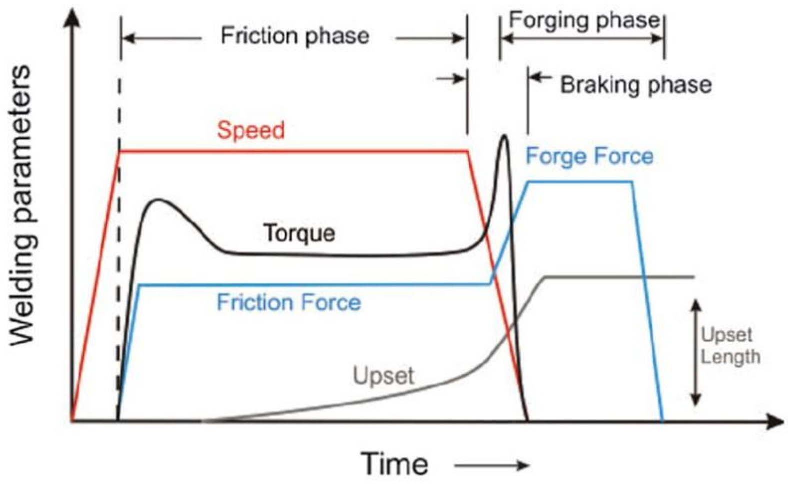


Fig. 11. Scheme of rotary friction welding [42]

Furthermore, linear friction welding differs from rotational one because of linear motion across the interface. The two pieces were bonded together and swiftly oscillated back and forth along their longitudinal axes while being subjected to high axial force during the linear friction welding process. The material at the interface becomes softer as a result of the frictional heat produced by the two components rubbing against one another. This allows the material to deform and flow plastically, creating a solid-state connection. This process consists of four stages (Fig. 12), where:

- Firstly, during the initial part of the process, two workpieces are moving linearly back and forth under pressure;
- Secondly, heat affected zone expands and wear particles are ejected from the contact interface in transition phase;
- Thirdly, in equilibrium phase highest temperature is reached and flash is formed;
- Finally, during the deceleration phase, the desired upset is reached and forging pressure is applied [43].

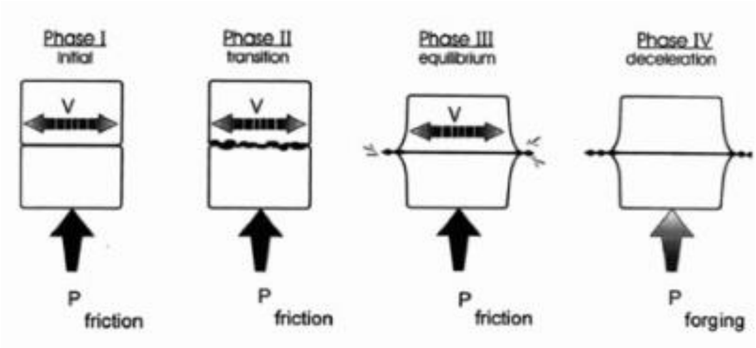


Fig. 12. Visualisation of linear friction welding [44]

Another example of welding is stir friction, when rotating tool is held under pressure against the component to be bonded. The pin scrapes against the two components during the stir friction welding process, producing frictional heat that softens the material at the contact and forms a plasticized zone. The plasticized material is then stirred and forced together to form a solid-state bond as the pin is swiftly driven through the joint [45]. Moreover, orbital friction welding is similar to rotary one, but main difference is that the axes of the two welded pieces are rotated simultaneously at the same speed and direction with a small distance offset in parallel longitudinal axes (Fig. 13). After a weld, the relative movement is stopped by bringing both pieces back to the machine's common axis, and the welding force is either kept constant or increased [46]. Finally, other untypical welding types are introduced as ultrasonic, explosive or vibration ones.

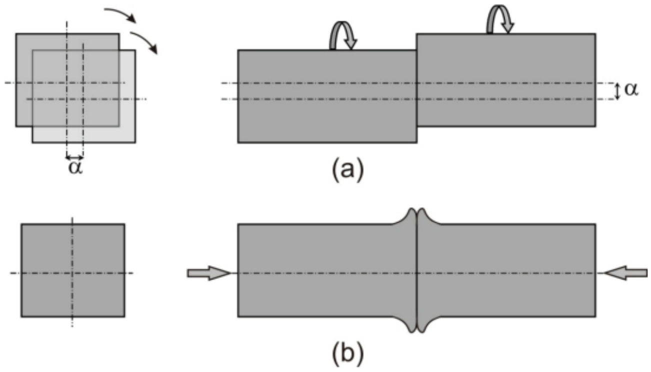


Fig. 13. Scheme of orbital friction welding, where a – friction phase with α axes offset, b – forge phase [47]

Concluding discussion about friction welding can be stated that it is highly efficient and reliable process, where wide range of materials can be used to bond, including metals, plastics and composites. It offers several advantages over traditional welding, such as high welding speeds, low energy consumption, high bond strength and no fluxes, filler material or gases are required. As technology continues to evolve, it is likely that friction welding will become even more widespread in various industries.

2.1.2. Other Types of Welding

Besides already analysed friction welding method, other types of welding are commonly used in manufacturing industries. Each method has its advantages and disadvantages, and the choice of technique depends on the specific application and the type of materials being bonded. Previously discussed methods were based on pressure and here some examples where mostly heat is applied to provide a permanent joint between components.

To begin with, arc welding is described as joining process, in which an electric arc forms between an electrode and a workpiece. Materials are fused together by the heat of the arc, and filler material may occasionally be added to boost the strength of the weld joint. The process of arc welding can be performed manually by a human welder or mechanically by robots or machines [48]. On the contrary, in gas welding, oxygen or air is combined with a variety of different gasses, including acetylene, propylene, methane, and others. This process uses a flame at a high temperature created by gas combustion, and it occasionally involves adding filler metal in a manner similar to arc welding. Comparing both methods can be stated that arc welding is mostly utilized for bulkier materials, whereas gas welding is more delicate and is used for thin materials [49].

Furthermore, resistance welding is such process where heat is produced when the workpieces are touched while a localized electrical current circulates. This indicates that pressure is used to ensure sufficient contact between the parts [50]. On the other hand, thermit welding does not require a current source of any kind. However, this joining is accomplished through a chemical reaction (thermite) between a reducing metal and metal oxide. When compared to arc welding, both resistance and thermit welding have a limited range of applications; for example, thermit welding is typically utilized for massive constructions like rail lines [51].

Finally, the ability to weld is crucial in numerous industries and is applied to create a variety of construction. Due to numerous applications different types of methods can be indicated. Thermit welding is used for thicker materials and generates higher-quality welds than gas welding, which is typically cheaper and results in strong bonding. Resistance welding is frequently used for spot and seam welding of thin materials, whereas arc welding is a very versatile procedure.

2.2. Tubing Types and Concerns

Generally, in Cambridge dictionary tube is described as “long cylinder made from plastic, metal, rubber, or glass, especially used for moving or containing liquids or gasses” [52]. Therefore, one of the main goals in joining tubes to create water or gas proof system where no leakage could occur. Moreover, it should be noted that there are various ways on how to join tubes, thus it will be discussed in favour.

To start with, piping industry is keep advancing, therefore numerous research are conducted and various types of connection are analysed. Multi-layer pipes are joined together via magnetic pulse welding, which uses electromagnetic forces (Fig. 14). A quick, repeatable operation without postprocessing, a sustainable solution, and a clean method all contribute to the low cost of this technique. However, it takes time to adapt and develop new products that incorporate magnetic pulse welding and requires proper control over process parameters [53]. Another research was made about investigating major pipeline failures and causes. The findings of comparing five various methods for assembling HSLA steel pipes (electric, laser, arc, and gas welding) revealed that poor welding creates a favourable environment for erosion, cracking, and wall thinning [54].

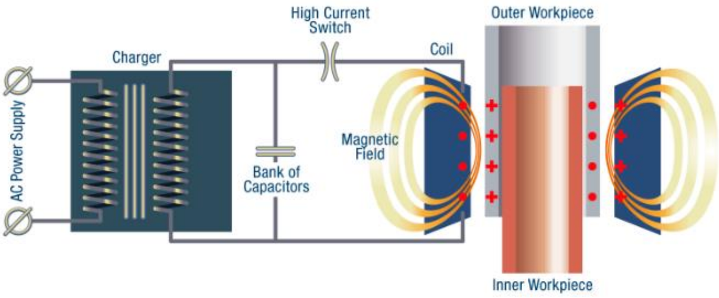


Fig. 14. Scheme of multi layer pipe magnetic pulse welding [53]

What is more, magnetic pulse welding is used for joining tubular structures made of aluminum and carbon fiber reinforced plastic. Positive findings from the study included great tensile and torsional strength of joints. However, due to the possibility of cold lap, this technique typically works for thin well tubes. [55]. Another option to assemble tubes is friction stir welding. This method advances in high bond strength, however, serious consideration was done in designing new tooling and readjusting parameters, such as rotational and weld speed [56].

Aside from welding, adhesive bonding is another option for assembling tubes. For instance, when examining bending behavior, the assembly of welded metal pipes revealed a substantial reduction in flexural stress when compared to pipes joined by fiber reinforced composites. It is claimed that employing such fillers while connecting pipes is highly beneficial and that this is the industry's greatest potential innovation [57].

Last but not least, tubing can be completed in a mechanical assembly way. For instance, shrink fit technology, which involves inserting one tube into a heated cylindrical component, has been studied by scientists. Due to the simplicity of the technology, this approach is used to attach a cylindrical clutch and a shaft. Unfortunately, the primary concern is related to the lack of sufficient tightness between cylindrical surfaces, and it is more difficult to alter technological parameters to ensure it [58]. Additionally, it is necessary to combine cylindrical elements of various diameters. Therefore, rotary swaging method is used when one tube is inserted into another axially rotating one and fitted under pressure or expenditure. However, that cannot be performed with the same diameter of tubes [59]. Finally, even under hydrostatic pressure self-piercing riveting can be used in joining tubes (Fig. 15). This method of connecting tubes works well since it is challenging to insert a die in an inner tube with limited space. It is also inexpensive and versatile for use with different materials [60].

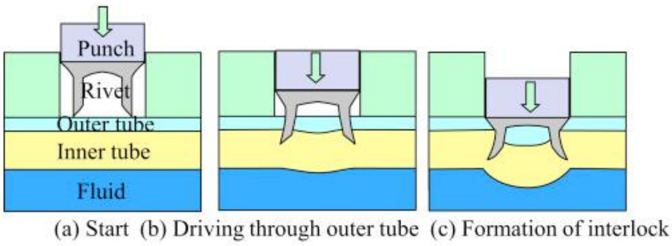


Fig. 15. Tube assembly with rivets [60]

To sum up, scientists are constantly developing methods of tubing. This is due to the shortcomings of most technologies, including erosion, cracks in welded connections, difficulty in implementing new processes, and others. All of the mentioned above, including various types of welding, assembly with adhesive materials and mechanical ways can be considered and tubing options.

2.3. Summary of Various Assembly Techniques

Assembly methods include mechanical, welding, adhesive bonding, and solvent welding. Mechanical assembly involves joining two or more parts of a mechanical system to form a functional unit, while adhesive bonding involves applying adhesive to the surface of the material to be bonded. Welding is a process of joining materials into one piece, and there are a variety of welding techniques to choose from. Evaluation criteria include capacity to repeatedly assemble parts, tooling depreciation, and durability. Adhesive bonding is used in aerospace and automotive industries to reduce weight and fuel consumption, but has drawbacks such as environmental factors and surface treatments. Welding is a useful method for attaching metal components, but it raises safety and quality control issues. Friction Welding (FRW) is a solid state welding technique that produces a strong long-lasting weld without the addition of flux or filler metal. Three process phases are indicated: friction, braking, and forging. Duration of forging phase is crucial to ensure the strength of the bond. Friction welding is a highly efficient and reliable process that offers advantages over traditional welding, such as high welding speeds, low energy consumption, high bond strength and no fluxes, filler material or gases. The choice of welding technique depends on the application and type of materials being bonded. Arc welding is used for bulkier materials, gas welding is used for thin materials, resistance welding is used for spot and seam welding, and thermit welding is used for thicker materials. Tubing is a long cylinder used to create water or gas proof systems. There are various ways to join tubes, such as magnetic pulse welding, friction stir welding, and adhesive bonding. Poor welding can lead to erosion, cracking, and wall thinning. Scientists are developing methods of tubing to address the shortcomings of most technologies, such as erosion, cracks, and difficulty implementing new processes.

3. Structured Problem Solving Application to Tubing Process

Nowadays industries are constantly improving their processes based on the principles of continuous improvement, where one of them – structured problem solving. The company “X”, that manufactures and supplies medical devices, follows Lean production system. Therefore, when faced with problems, employees show initiative and solve problems in a structured way. One of the problems arising now is the large number of defects in the rotary friction welding process, which was solved using the A3 report.

In company “X” rotary friction welding is applied to assemble a urine collection bag and a catheter. For this semi-automatic machine is used that can operate 10 parts per minute in average of 80% overall equipment efficiency (OEE). In general, machine is combined of 2 automated station and 3 manual handling stations (Table 1).

Table 1. List of station of semi-automatic rotary friction welding machine

Manual handling station	Station 1 - Infeed	Operator manually load a catheter and prior folded urine collection bag onto infeed conveyor.
Automated station	Station 2 – Pick and Place	Transfer servo picks loaded catheter and folded bag and places into designated position. After welding transfer servo picks welded assembly and places onto outfeed conveyor.
Automated station	Station 3 – Welding	Loading table servo inserts catheter inside bag port and spindle servo rotates it to weld it.
Manual handling station	Station 4 – Outfeed	Operator manually unload assembly from the conveyor.
Manual handling station	Station 5 – Banding	Operator perform final bag folding and puts it into banding station.

A visual representation of the process is initially generated (Fig. 16) in order to tackle the issue more precisely. There are 15 steps in the process, most of which are completed by hand by the operators. For instance, production workers fold bags by hands, then loads into machine, picks them up from unloading conveyor after connecting, performs the final bag fold and ties product with banding tape. In addition to all this, in-process quality check is included into the process, which are performed after the bag is folded and at the end of the assembly process. Visual inspection and destructive testing, where tensile tests using a dynamometer are used to determine the strength of welding seams, are performed.

As a result of high variation of raw materials and manual work, this welding process is unstable and sensitive to changes in regular production. Thus, challenges, like poor product quality, low machine performance, are constantly arising. Last straw was taken after risen Nonconforming Material Report (NCMR) on 15th of December in 2022 due to narrow welding seams found during in-process check, therefore, an investigation was started.

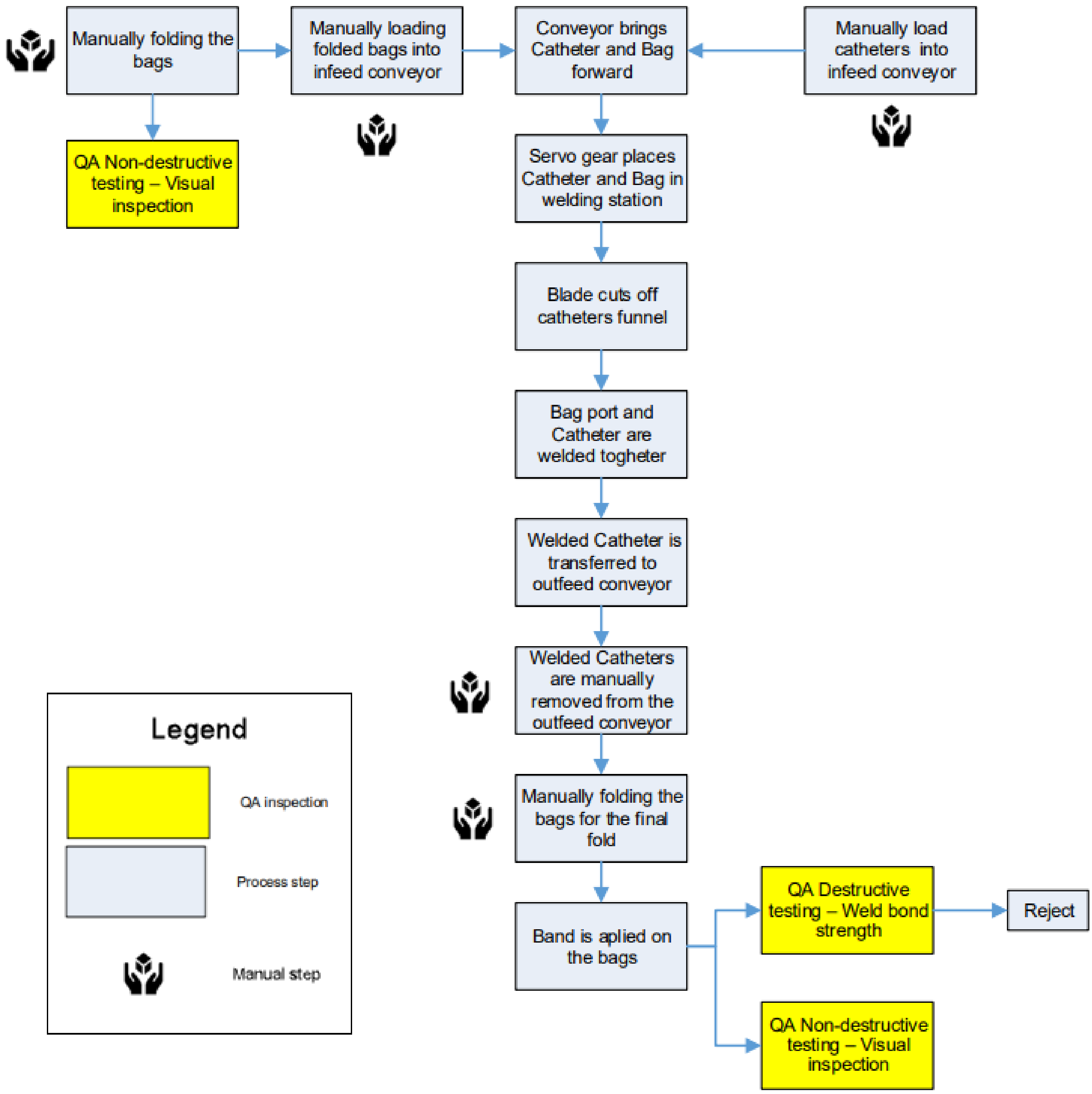


Fig. 16. Flow chart of rotation friction welding process in company "X"

3.1. Materials and Methods

In this investigation polyvinylchloride (PVC) tubes were utilized to analyse tubing process. PVC is described as "the homopolymer of vinyl chloride". Due to PVC widely applicable properties (Appendix 1), this thermoplastic is frequently used, including:

- Food packaging,
- Medical appliance (transfusion bags, tubing),
- Outdoor applications (window frames, rainwater gutters, covers),
- Electrical insulation [61].

Moreover, tubing process consists of catheter tube (Fig. 17) and urine collection bag port tube, which are bonded in rotary friction welding manner (Fig. 18). Catheter funnel is made of PVC (98%) and 2% of colorants, which depends on the charrier size (CH08 Blue, CH10 Black, CH12 White, CH14 Green, CH16 Orange). Attachment port of the bag is made co-extruded plastics, where inner tube material is PVC and outer – ethylene vinyl acetate (EVA). According to material compatibility, high weld quality can be achieved between PVC materials [61].

Fig. 17. Example of a catheter

Fig. 18. Example of catheter and urine collection bag tubing assembly

What is more, a decision to employ the A3 Report tool is made in consideration of calculations (Table 2). The Severity, Occurrence, and Control sections in the Impact Assessment table are scored from 1 to 5 (where 1 is no impact and 5 is significant impact) in place of the raised concern. The impact of a problem on a project's budget, time, or risk to the quality of the final product or process is used to determine severity. Thus, the score is three due to impact on product quality and increased cost. Moreover, occurrence is measured on how often the issue occurs, therefore, score is three because of numerous but not periodically elevated NCMR. Lastly, it is important to indicate how control takes place and for capturing product defects in production quality control is conducted. Finally, after multiplying the three values, the final score is 18, which is between 10 and 30, indicating that the problem requires the implementation of the A3 tool.

Table 2. Impact Assessment Table

Issue to Product or Process	
Severity (S)	**Score**
Product loose part of functionality OR No user effect but impact on business	**3**
Occurrence (O)	
Often, but at random (e. g. product impacted at start up / re-start)	**3**
Control in place (C)	
More than one control element in place (e. g. in process inspection + QA inspection)	**2**
Final score (S*O*C):	**18**
Decision:	**A3**

Generally, A3 report is based on DMAIC (Define – Measure – Analysis – Improve – Control) method (Fig. 19). It is not a secret that such technique aids in structuring the problem at hand by assisting the user in discovering an approach for problem analysis and solution [62] What other tools are used for the research, it is discussed below.

Starting with, Is / Is Not Analysis is used while describing the problem by asking various questions (Who? What product? When? Where? How often? In what process?) to narrow down specific on the issue. It is expressed that when the problem statement is clearer, the more quickly a problem is resolved. Additionally, Root Cause analysis is inevitable in problem solving. There are various tools and ways on how to reach the primary cause of the problem. For instance, Fishbone diagram is a graphical method for displaying the various causes of a certain occurrence or phenomena or five WHY – simple way of getting to main cause by asking questions [63].

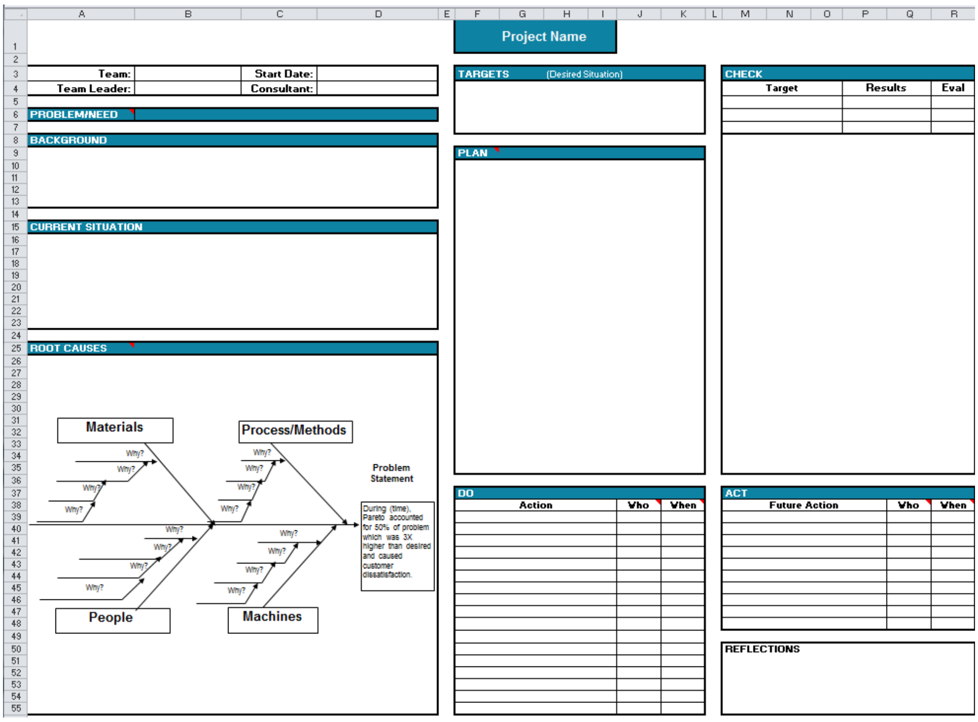


Fig. 19. A3 report template [64]

3.2. A3 Report – Product Weld Width Deviation

To begin with, first A3 solving session was conducted, where team was selected, problem title formulated "Product Weld Width Deviation" and duration was set – 3 months (see Appendix 2). Team is listed:

- Project Engineer (PE). PE has qualified the machine and process, conducted various research and has gained a lot of expertise in rotary friction welding. PE was elected to be A3 facilitator.
- Maintenance Supervisor (MS). MS is leading maintenance technicians' team, who are performing spare parts wear investigation and replacement.
- Manufacturing Engineer (ME). ME is subject matter expert and he / she manages equipment in regular production.
- Quality Assurance Engineer (QAE). QAE has validated this process and, he / she is aware of not only quality assurance, but quality control inspection as well.

3.2.1. Problem Description

The DMAIC methodology states that the problem must first be defined and team has chosen tool Is / Is Not (Table 3). Determining what is included and excluded from the problem or situation is helpful because it helps the challenge become more clearly focused. As a result, it was decided to focus on defects with weld widths of less than two millimetres (Fig. 20) rather than more significant flaws like swarf or scratches on bag surfaces. Moreover, narrow weld occurs in welding process and not in other machines stations that are already described (Table 1). It is stated that only manufacturing team is affected. This is due to the fact that flaws were discovered during a routine manufacturing quality check and not during equipment validation. But the pattern showed that narrow welds do occur frequently but not consistently across all product sizes. Despite the fact that within a 24-hour period, 10,000 parts are manufactured and, on average, 100 units are rejected, costs are increased. Finally, a problem statement was developed, stating that weld deterioration accounts for 10% of additional cost rate when weld width does not match product standard requirements.

Table 3. Problem description regarding Is / Is not analysis

	IS (Observation):	**IS NOT (Observation):**
What is the defect / problem?	Weld width is lower than 2 mm	Other major defects
What processes?	Rotation friction welding	Packaging
Where is the process?	All rotation friction welding machines	Packaging machines
Who is affected?	Production	N/A
When did it happen?	NCMR raised on 15th of December 2022	During equipment validation
How frequently did it happen?	NCMR's raised on 2022-12-15, 2022-12-16, 2023-01-09, 2023-01-20	Once a week
Is there a pattern?	Varying quantities, but every shift; all catheter sizes CH08, CH10, CH12. CH14, CH16	Only size CH10
How much is it costing?	10% of total produced quantity	N/A
Problem statement (from the IS column): Products with narrow weld have been found by QA technicians on 2022-12-15 during production. Weld width fails product specification (No. XXXX) requirements and cause up to 10% additional cost.		

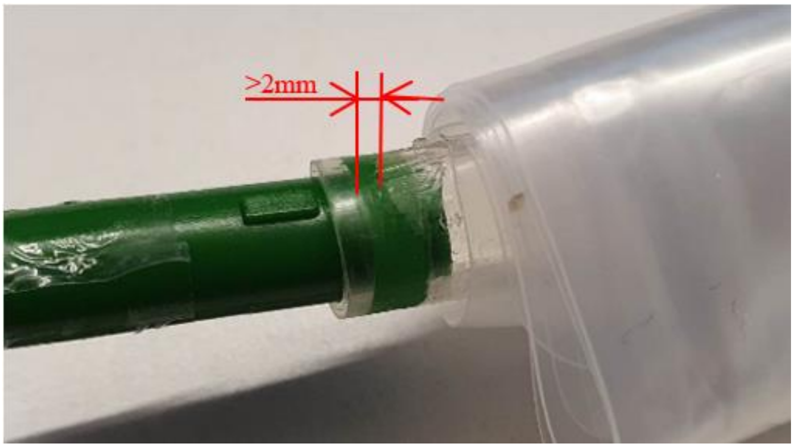


Fig. 20. Example of narrow weld

3.2.2. Current Situation Analysis

What is more, it is critical that the situation analysis be measurable and grounded in facts, data, and evidence. Therefore, data of weekly production waste rate was collected between the middle of November in 2022 and the middle of January in 2023 (Fig. 21). It should be mentioned that data of Week 51 and Week 52 in the year of 2022 were not evaluated since it was Christmas holiday period and production line was shut down. Moreover, calculating overall waste such defects are included: damaged catheter and bag, contamination particulates (hair, grease, fuzz), quality samples for destructive testing and others. It could be seen that starting in Week 49, the overall scrap rate exceeds the objective (1%) and then significantly rises through Week 2. However, narrow weld defects make up a substantial amount of total scrap and cannot be overlooked.

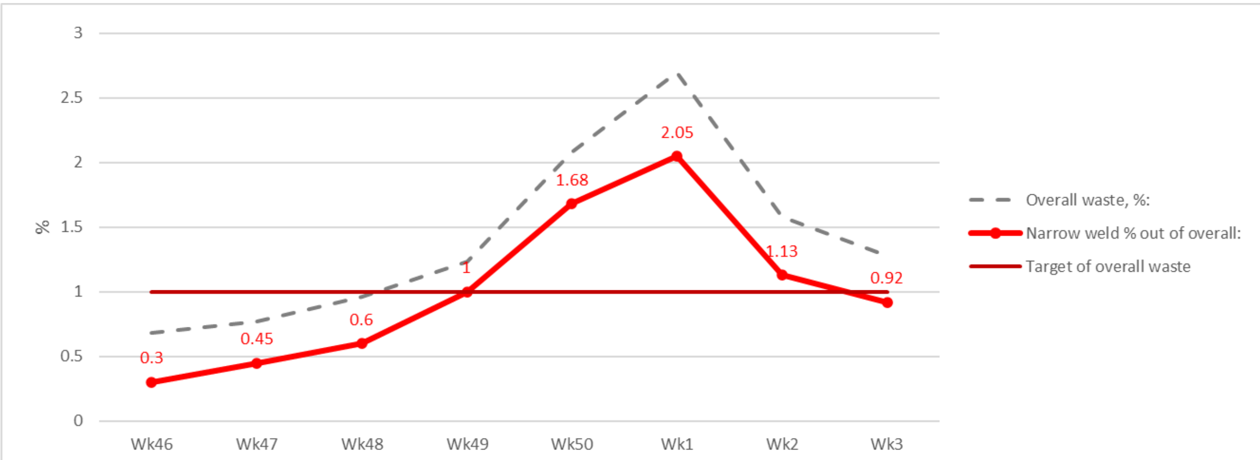


Fig. 21. Graph of narrow weld cases during 2022 Week 46 till 2023 Week 03

After investigating current situation, objective of A3 research is indicated according to SMART method. This method defines that goals must be formulated in specific, measurable, achievable, realistic and time-related manner. Therefore, by the beginning of April 2023, the A3 aim is to identify the primary problem and eliminate or reduce below 0.5% defects of weld width lower than 2 millimetres.

3.2.3. Root Cause Analysis

Nevertheless, the Ishikawa diagram (Fig. 22) is used for rootcause analysis using the 6M technique. This indicates that every reason conceivable is taken into account from the perspectives of labour, machinery, materials, methods, measurements, and mother nature. The following symbols are employed for convenient progress tracking:

- Impact on the problem is color-coded (red – highly likely, yellow – potential, green – no link),
- Geometrical figures for tracking investigation steps (green triangle – analysis of the reason, blue rectangle – following action).

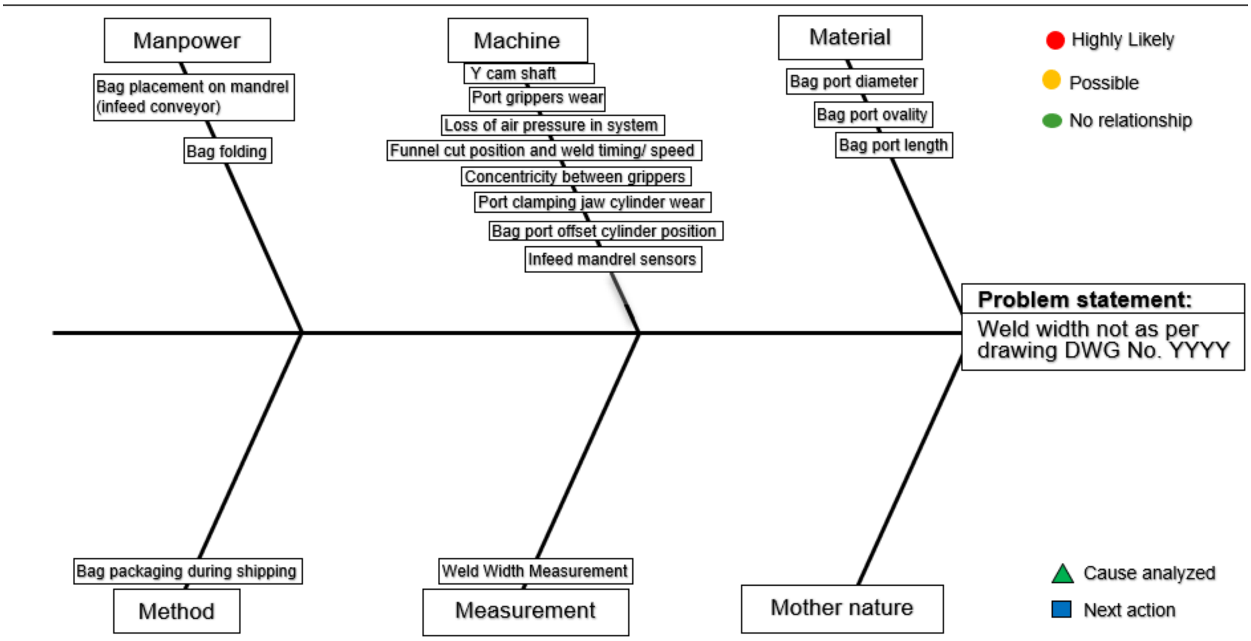


Fig. 22. Ishikawa diagram before cause analysis

The overall picture demonstrates that the mechanical components of the equipment and process parameters most likely influence how narrower seams occur. Moreover, the reliance on manual labour and raw materials is far less prominent. And the possibility of the process method or the technique of measuring the weld width is not ruled out.

3.2.4. Potential Solutions Development

Furthermore, after identifying possible causes investigation has been conducted. In the action log (Table 4), where owners were allocated and status was monitored, all causes have been listed. The results of the analysis are color-coded similarly to the cause-and-effect diagram (Fig. 22). Four main factors that have a significant impact on narrow welds were identified:

- Mechanical part wear,
- Part installation,
- Quality of raw material,
- Manual bag folding.

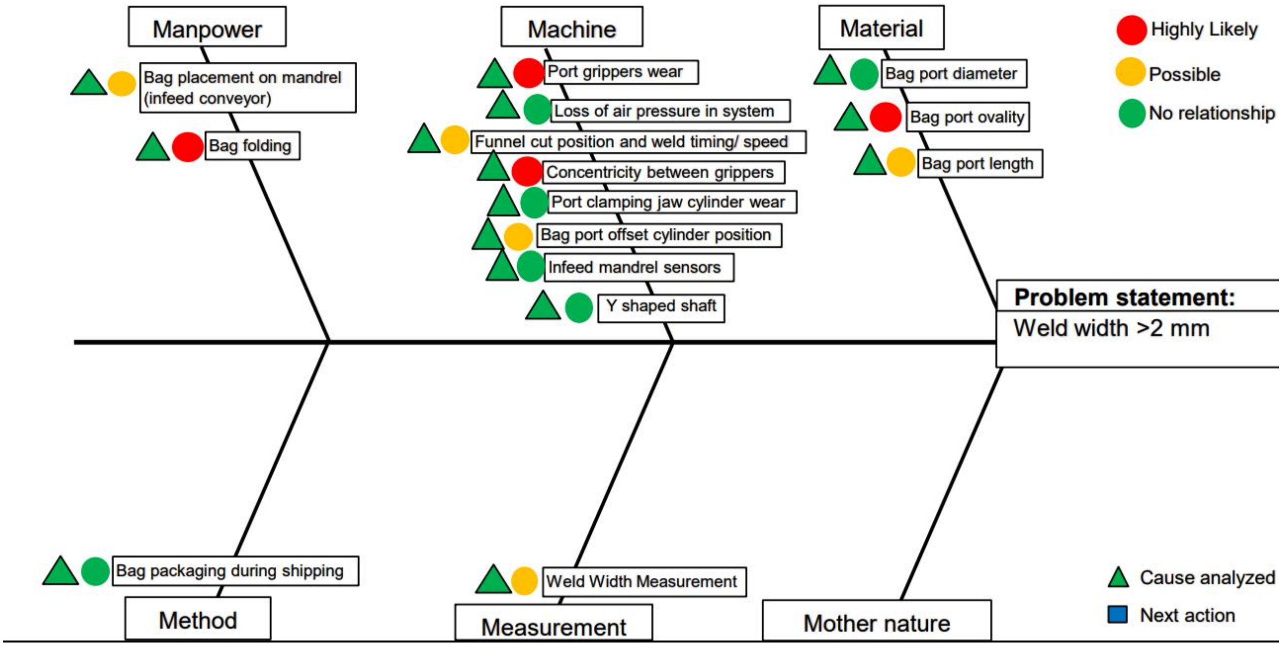


Fig. 23. Fishbone diagram after causes investigation

Table 4. Action log based on fishbone diagram

Cause Investigation:		No relation		Contributes to the problem		Direct cause

#	Investigation	Owner	Results / Conclusion	Status	Result
1	Y shaped shaft	MS	It was observed that shaft is bent. Replaced with new one. Bent shaft increases friction in bag holding mechanism, decreasing applied force.	Closed	
2	Port gripper wear	MS	Grippers worn out. Gap between Y cam shaft top surface and grippers square hole is 0,05mm (for new one should be 0,01mm). New parts ordered, item added to troubleshooting guide.	Closed	
3	Loss of air pressure in system	MS	System checked for leaks - no leaks observed. Event added to monthly Preventive Maintenance tasks list.	Closed	
4	Funnel cut position	PE	Funnel cut position should not exceed product specification requirement. If exceeded – funnel edge will block entrance to bag. If too low – cut will not block path for swarf to enter collection bag. Recipes changed, item added to troubleshooting guide.	Closed	
5	Spin start point	PE	Spin start position defines number of revolutions applied during weld. If number is low, head will start rotating earlier, decreasing weld time. If number is high – bag will not be spinning as funnel enters port. Spin start point should be ~10 points lower that weld position. it will ensure that bag will start rotating just before funnel enters port. Item added to troubleshooting guide	Closed	
6	Insert and weld speed	PE	Insert speed has no noticeable impact to weld quality. Weld speed describes how quickly funnel get inserted into bag port. When speed is high, funnel is inserted very quickly, increasing weld time, but it increases flashes as well. Low speed reduces weld strength. Value of 70±5 is recommended. Item added to troubleshooting guide.	Closed	

Cause Investigation: **No relation** **Contributes to the problem** **Direct cause**

#	Investigation	Owner	Results / Conclusion	Status	Result
7	Concentricity between grippers	MS	Concentricity measured to be ~0,25 mm for Machine No.2 and ~0,5 mm for Machine No.1. Vendor recommended max value – 0,1 mm. Machine No.2 concentricity improved by realigning rotating head. It was observed that main shafts are bent on both spin welders. New parts should be ordered and installed	Closed	
8	Port clamping jaw cylinder wear	MS	Cylinders replaced. Worn-out cylinders cannot ensure enough force on bag port to keep it in place. Item added to monthly Preventive Maintenance tasks list.	Closed	
9	Investigate bag port offset position	PE	Vendor recommended port offset position is 0.6 to 1.0 mm. Higher offset position flares the port out, but positions weld closer to bag seal, where ovality of port is increased. Smaller than recommended value improves weld quality but increases risk of bag being pushed into rotating head as funnel enters port. Offset set to 1.0±0.2 mm for all machines. Item added to troubleshooting guide.	Closed	
10	Bag port diameter	ME	Port diameter measured using gauges. Results show that diameter is within tolerance 7.5±0.15. No noticeable impact to weld quality. No further actions required.	Closed	
11	Bag port ovality	QAE	Port ovality measured per Raw Material specification. Products with increased deterioration failed to meet ovality requirement. Investigation required to determine deterioration duration for oval ports and round ports. Extent of defect needs to be communicated to bag supplier.	Closed	
12	Bag port length	ME	Bag port length measured per Raw Material specification. Bags that are at lower specification limit 8.5±1 mm have increased risk of narrow weld and deterioration as weld is placed closer to bag seal. Also folded bags get pinched by port grippers. Information communicated to Team Leads and Operators to raise awareness	Closed	
13	Bag folding	PE	Bag folding has noticeable impact to quality. Study executed to determine folding impact to quality. If 1st fold is incorrect – port grippers pinch bag material and will not ensure roundness of port, thus increasing risk of narrow weld and deterioration. 2nd and 3rd folds have less impact to quality. Information communicated to Team Leads and Operators to raise awareness.	Closed	
14	Weld width measurement	PE	Weld width is measured differently between shifts. Gauge has been designed and calibrated to eliminate cause.	Closed	
15	Clarify reason for >2 weld width requirement	QAE	If the weld thickness (2mm in this case) is greater than the wall thickness of the tube (attachment port), then the tube is the weakest part of the assembly, not the weld. The wall thickness of the attachment port is 1 mm, a factor of safety of 2 applied to make weld thickness 2 mm	Closed	
16	Infeed mandrel sensors / placement	MS	Sensors ensure repeatable bag and funnel position on infeed conveyor. When sensor values are incorrect, part presence will be incorrectly accepted. Part will be placed incorrectly into rotating head, increasing risk of narrow weld. Sensor position and values check added to weekly Preventive Maintenance tasks list.	Closed	

Additionally, it is evaluated that mechanical units, which supports tubes during rotation and fusion, are primarily related to the quality of fusion. In the visual below (Fig. 24) in dashed yellow square the gripper assembly for holding the catheter tube is shown. It consists of a moving table with servo drive and gripper assembly. Under the blue dashed square on the right there is a spindle rotating with the aid of a servo drive and a gripper assembly. Grippers, which hold folded bag and its tube, retract and extend on the Y-shaped shaft, which was observed to be worn. Worn grippers wobble and are unable to grasp the bad tube firmly. As a preventive measure, this observation was indicated in the troubleshooting guide and new parts were ordered.

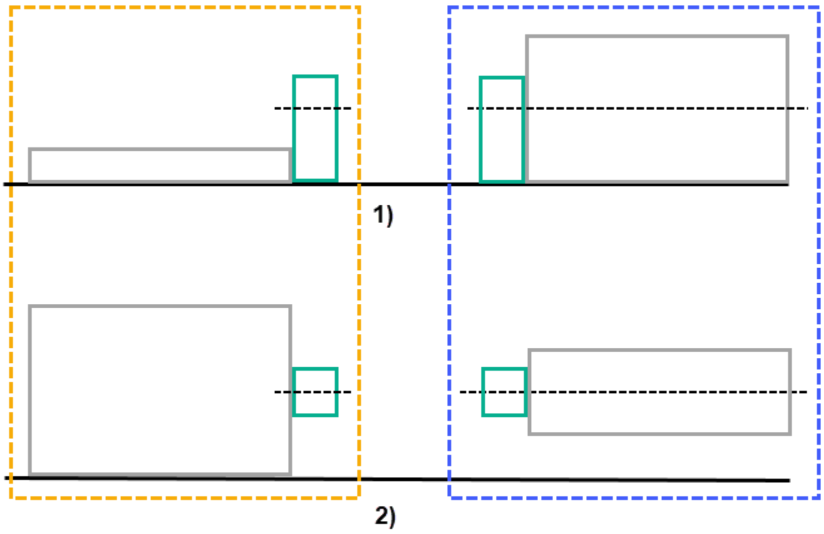


Fig. 24. Welding station sketch of rotary friction welding machine in company "X": 1) front view; 2) top view

Furthermore, besides worn parts, the accuracy of components installation additionally plays a crucial part in welding quality. The concentricity between retained catheter and bag tubes is impacted by improper placement. The catheter is pushed unevenly and welding begins on one side rather than the entire cylindrical surface when there is a substantial deviation from concentricity. One of the causes of an uneven welding seam is this, and in some situations, it can indicate the product no longer meets the specifications.

What is more, PVC is malleable and simple to deform. For instance, deformations can occur during production process of the bag supplier (after cutting the tube into smaller pieces or after it is fussioned into the bag) or due to transportation, as the tubes may get compressed when urinary collection bags are loaded in large quantities. Investigation reveals that employing oval tubes most frequently results in narrow welds. If the catheter tube outer diameter is greater than the inner diameter of the bag tube at a depth of one centimetre, the port is considered to be oval (Fig. 25). This is lead to the conclusion that a large number of defective bags enter regular production because the sample size used to check for ovality during incoming inspection is too small. As well, supplier is informed about the non-conformity of their production and remedial actions are taken.

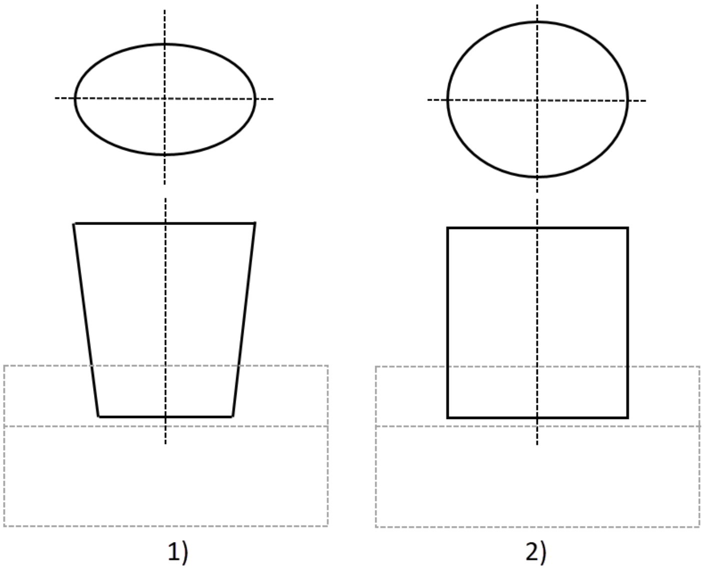


Fig. 25. Sketch of tube fussioned into bag: 1) oval, 2) round

Lastly, as manual processes are challenging to control, there are frequently human errors made, and this procedure is not an exception. This is because operators are folding bags with their hand and major fault happens due to rush and / or inexperienced worker. Operators must maintain a certain pace because they have to work in tandem with the equipment and if there no folded bags otherwise machine must be stopped. Also, the bag surface is slick, thus, bending and pressing may cause the corners to slide. It was discovered that a narrow weld tended to form more frequently if the first bending was done transversely. This can be justified by the fact that the edge of the folded bag rests on the bag tube and it is not fully pressed in the grippers during welding. Using automated bag folding machines is the greatest approach to stop human error.

3.2.5. Countermeasures Implementation

Moreover, ten countermeasure actions were implemented and logged based on the potential solution analysis (Table 5). Five out of ten actions are related to mechanical aspects of the equipment (1, 2, 7, 8, 10). The other tasks are related to product functionality (2, 9) and quality concerns (4, 5, 6). After equipment evaluation it was decided to update Preventive Maintenance check sheet by including concentricity observation and replace worn out parts. What is more, weld deterioration tendency was observed comparing assemblies with oval and round tubes of bags. Based on the results it was decided to inspect the quality of the bags more carefully and continue production with ones of acceptable quality. Another point is that weld width is measured with a calibrated ruler in quality control. This means that measurement results are inaccurate due to the method of measuring cylindrical surface. Because of this, calibrated gauge was created to evaluate whether weld width is less than 2 milometers.

Table 5. Countermeasures log

#	Action	Owner	Completion date
1	Add concentricity check to weekly Preventive Maintenance tasks	MS	2023-02-13
2	Order and receive new parts to recover alignment	PE	2023-03-15
3	Investigate how long deterioration continues. Test against acceptable quality bags	PE	2023-02-20
4	Communicate quality issues to bag supplier	QAE	2023-02-24
5	Determine if QA in-process inspection procedure needs to be changed	QAE	2023-03-13
6	Continue production only with acceptable quality bags	PE	2023-02-16
7	Install new bag support grippers	MS	2023-03-09
8	Install new rotating head assembly	MS	2023-03-16
9	Investigate manual bag folding impact	PE	2023-02-08
10	Produce and calibrate 2mm weld width gauge	ME	2023-02-24

3.2.6. Improvement Verification and Standardization

Lastly, the effectiveness of the countermeasures and solutions were verified. To start with, there was no additional Nonconforming Material Report arisen since the last one in 20th of January. Then, additional quality inspection was performed after 24 hours post production. This was completed to evaluate possible weld deterioration cases and there were no narrow weld samples. Moreover, it was observed that between week 12 and week 17 in 2023 neither the target of narrow weld cases (0.5%) nor of overall waste (1%) were exceeded (Fig. 26). Finally, actions for standardization were implemented: troubleshooting guide was updated and related personnel were trained to inspect bad quality raw material or to take reactive actions to eliminate narrow weld defect.

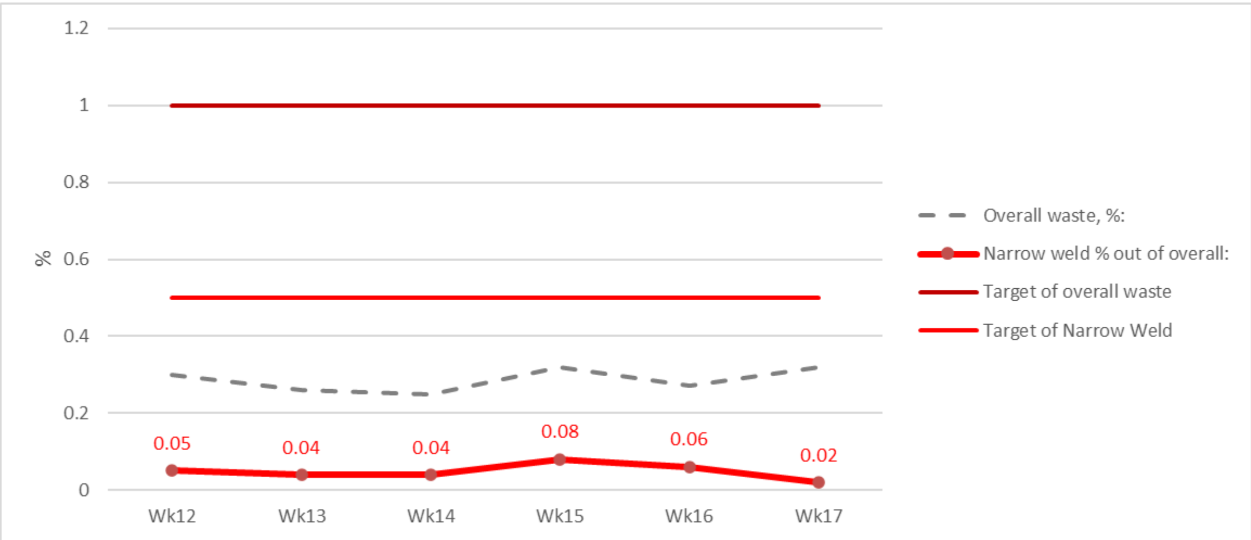


Fig. 26. Graph of narrow weld cases during Week 12 till Week 17 in 2023

Taking everything into consideration, research of product weld width deviation was executed according to the principles of DMAIC methodology. It was found that there are four main causes of narrow weld defect, which includes machine components, quality assurance and control concerns and raw material issues. Implemented countermeasure actions revealed positive results and investigation target has been met.

3.3. Alternative PVC Tubing Solution

Based on the analysis made above, rotary friction welding causes numerous challenges, which increases product primary cost, machinery downtime and possible more customer complaints due to poor quality product. Besides this, it is inevitable to maintain and / or improve position in the market for the business. For this reason, company "X" is taking measures to find innovative solutions for products' enhancement in order to remain competitive in medical industry.

One of the product developments is improving assembly process for connecting catheter and urine collection bag tubes. This improvement is based on the mechanical connection principle – snap fit. Snap-fit is based on the locking technique, when elements of a specific design are joint, while pushing in force. Comparing to rotary friction welding process, snap-fit requires following changes:

- In design of raw material geometry,
- In design of equipment parts,
- In software.

To begin with, to make an appropriate connection in a snap-fit assembly geometrical features of components are a crucial aspect. For manufacturing catheter products the most critical surfaces of the elements are:

- External diameter of catheter funnel (Fig. 27),
- Internal diameter of urine collection bag tube (Fig. 28).

For example, outer diameter of catheter tube can not be wider than the internal diameter of bag tube. Then the rib with draft angle must not be narrower than connection shoulder of the bag port. However, limitation of maximum catheter rib diameter should be considered in order to actually fit inside collection bag tube. Nevertheless, manufacturing process of the raw materials must be evaluated as well. It is chosen to cast both tubes for the catheter and urine collection bag. Therefore, casting mold geometry and tolerances of cavity dimensions must be considered. Moreover, composition of the material should be considered plastic enough that catheter tube structures be able to deform and regain formal form after insertion. What is more, due to sensitive information of company "X" the chosen material and the dimensions of modelled snap-fit features shall not be publicly shared.

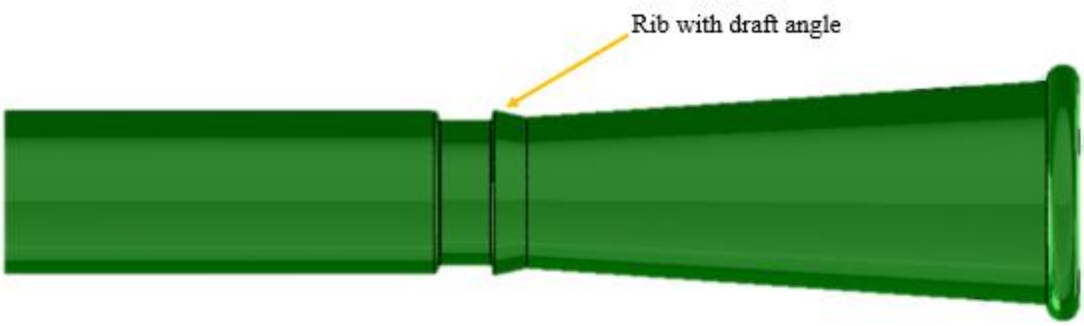


Fig. 27. Catheter model for snap-fit

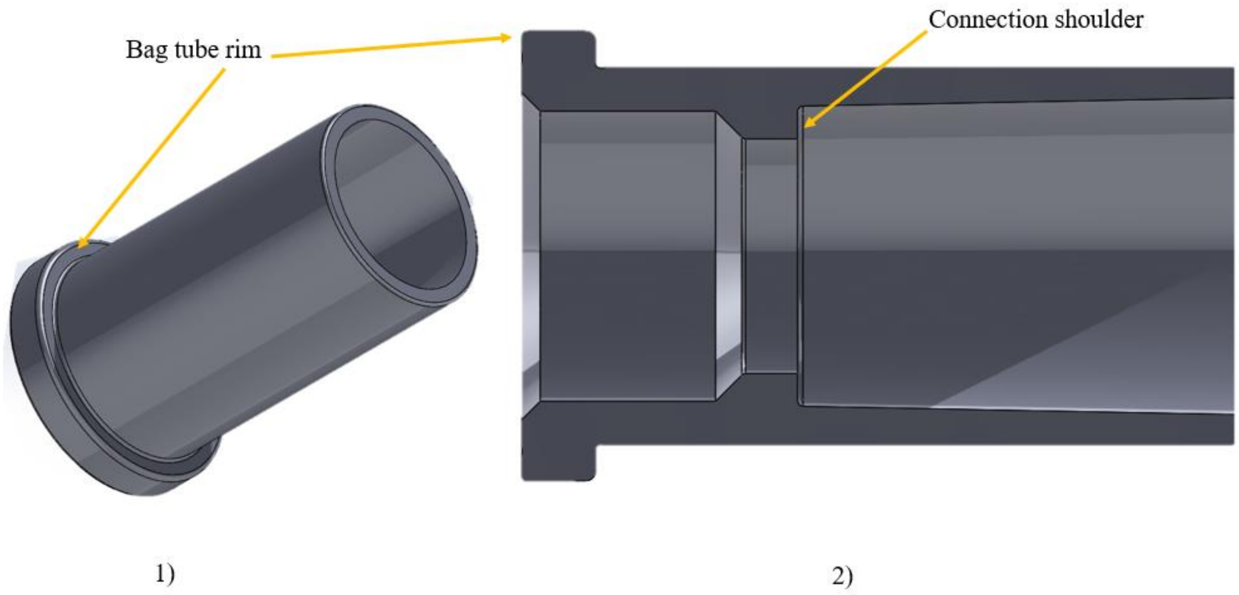


Fig. 28. Model of urine collection bag tube for snap-fit: 1) isometric view; 2) section view

Moreover, one the goal for company "X" is to use already installed equipment efficiently for following development. Therefore, the decision was made to convert an already mentioned rotary friction welding machine into a snap-fit assembly one. Considering that other process steps remain the same, besides welding station, thus, machine station description is applicable for the new product production line (Table 1). Furthermore, several servo drives are used to transfer components from one station to another and to make an assembly. Because of the need of sufficient power to insert tube into port, power of servo gears was evaluated, and it is stated that it is acceptable to perform snap-fit connection. Another thing is that several mechanical parts must be modified as they are marked as green symbols in Fig. 24. The parts are:

- Catheter tube grippers,
- Urine collection bag tube grippers.

Catheter and collection bag must be clamped tightly in order not to move out of the grippers during insertion. As a preventive measure from unnecessary movement in clamps, bag tube rim (Fig. 28) was developed. The rim is the widest part of tube and it is used to hold onto the frame of the clamps during insertion.

Nevertheless, businesses do not make straightforward product changes by instantly switching from old stock to new one. Especially in medical industry, customers are highly reliance on constant product features because it is a struggle to discover suitable tool for their symptoms or conditions. Consumers prefer using the same medical device as long as possible rather than keep changing and trying new ones. Therefore, marketing team must prepare loyal customers for upcoming changes: conduct various surveys, advertise and inform about new features of the product, make a possibility to try and examine it before fully releasing to the market.

In order not to lose potential clients, company should set a strategy for product transition. This means that production capacity must be calculated on how long and in what quantities catheter assemblies made in rotary friction welding approach should be manufactured before fully switching to snap-fit assemblies. For this reason, chosen equipment should be suitable for performing both processes: welding and mechanical joining. Based on the recent data, maintenance technicians and operators conduct process changeover in on average 65 minutes, including tooling change, mechanical adjustments and preparation for production start. The duration is considered too long that increases machine downtime per shift.

Finally, besides material and mechanical transition, software updates are needed as well. In the sequence of process steps spinning of welding spindle is provided as it is not needed for snap-fit connection. For rotary friction welding the part of sequences consist of such conditions:

IF catheter is pushed till INSERT position

AND

IF folded bag is placed in spindle

AND

IF bag port clamps are retracted

THEN catheter is pushed till WELD position

AND

THEN spindle starts spinning.

For mechanical joint spinning is not required, therefore the process sequence is changed to:

IF catheter is pushed till INSERT position

AND

IF folded bag is placed in spindle

AND

IF bag port clamps are retracted

THEN catheter is pushed till SNAP-FIT position.

It can be seen that one sequence step is eliminated, therefore, one product production cycle time is reduced. It is calculated that assembling catheter and bag in mechanical joint machine can perform in 11 parts per minutes compared to welding – in 10 parts per minute. This mean that changing the tubing process, quantity of produced units per shift can be increased by 10%.

Furthermore, according to process flowchart (Fig. 16) the steps of mechanical connection are following:

- Manual raw materials infeed,
- Catheter is cut (Fig. 29),

- Catheter is inserted into bag port (Fig. 30),
- Pick and place unit places onto conveyor,
- Manual assembly unload from conveyor and banding.

Fig. 29. Catheter tube after cutting

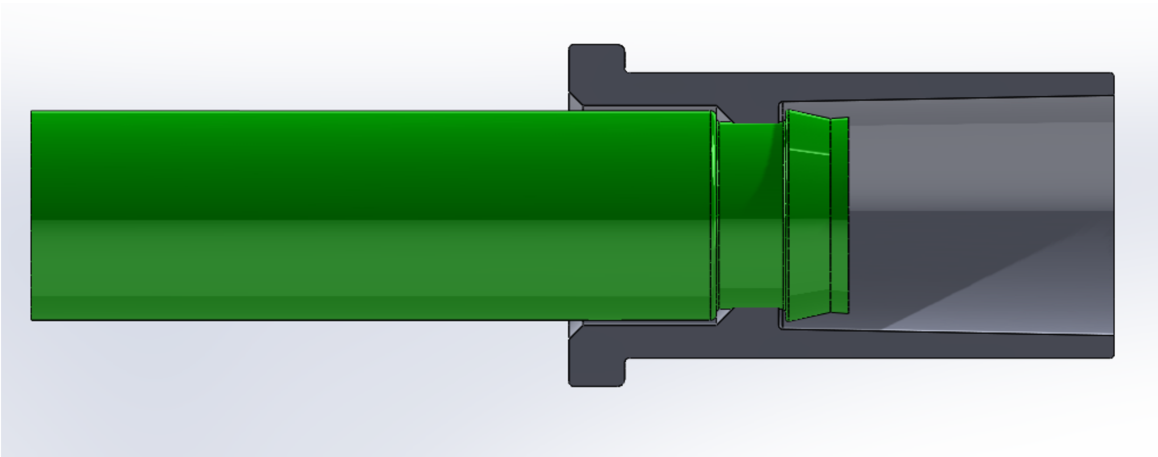


Fig. 30. Snap-fit connection

Overall, although the production process for snap-fit is uncomplicated, it allows to achieve higher manufacturing results. It is not difficult to modify the equipment in mechanical and programmable manner, but the idea of raw materials design is crucially significant. Welding has already come a long way and the company hopes to establish a new product to loyal clients and attracts new ones.

3.3.1. New Process Risk Management

According to the quality management system that is followed in company “X”, the risk management is a must to evaluate new process development. One of the risk control tools is Failure Mode and Effect Analysis (FMEA), which is a structured approach to detect potential flaws in design of a product or process. Therefore, new product development team applied FMEA and ranked possible risks according to probability and seriousness from low to high (Table 6). Risks can be categorized as machine, material or employee skills related.

Table 6. Snap-fit Process Failure Mode and Effects Analysis

No.	Potential risk	Risk effect	Impact	Probability	Monitoring actions
1	Catheter can slip from grippers while inserting into bag port	Catheter and urine collection bag is not assembled	Medium	High	- Design catheter grippers with acceptable gripping diameter - Design a wedge-type geometric onto catheter cylindrical surface and grippers accordingly - Evaluate catheter various percentage slippage material
2	While inserting catheter, bag port can be pushed out	Catheter and urine collection bag is not assembled	Medium	Medium	- Adjust pick and place parameters that wider part of the port is out of gripping zone. While inserting, wider bag port zone must rebound onto gripper housing
3	Not enough power of servo drive to insert catheter into bag port	Catheter and urine collection bag is not assembled	Medium	Low	- Evaluate snap fit power requirement and check if current servo drive is sufficient
4	Due to machine wear axiality between grippers can be lost	Catheter and urine collection bag is not assembled	High	Low	- Axiality check between grippers include in weekly preventive maintenance tasks
5	Wrong insert position set up	Catheter and urine collection bag is not assembled	Medium	Low	- Perform process validation - Manage access to position change between different employee positions
6	Wrong cut position set up	Catheter is without snap-fit connection	Medium	Low	- Perform process validation - Manage 0access to position change between different employee positions
7	Catheter is damaged during insertion	Blockage on catheter fluid path	High	Low	- Perform process validation; - Consider accessible hardness material
8	Snap-fit connection is not tight enough	Urinary leakage can occur	High	High	- Evaluate suitable raw materials dimensions and its tolerances - Consider using gasket-type of element
9	Longer time to train personnel	Lower equipment efficiency	Low	Low	- Prepare work instructions - Schedule time to train associates

For instance, there is a chance that production workers make unacceptable parameter adjustments. This means it can cause unsuccessful assembly performance, where either a catheter tube is cut too much, or catheter is transferred not deep enough to reach bag connection shoulder feature. For this reason process qualification have to be executed, in order to develop appropriate parameter range. What is more, catheter can get smashed during insertion, which causes blockage of urine fluid path for consumer. Based on evaluation, damaged catheter can appear in rare occasions, however, it may cause a major impact to product functionality.

Furthermore, it is advised to set priority list for potential risks before managing and implementing monitoring actions. One of the reasons for prioritising risk is limitation of human resources and schedule frame. The other thing is that it is crucial to begin managing risks based on their possibility to occur and seriousness. Thus, a probability and impact matrix is a suitable approach to arrange risks in priority manner (Fig. 31).

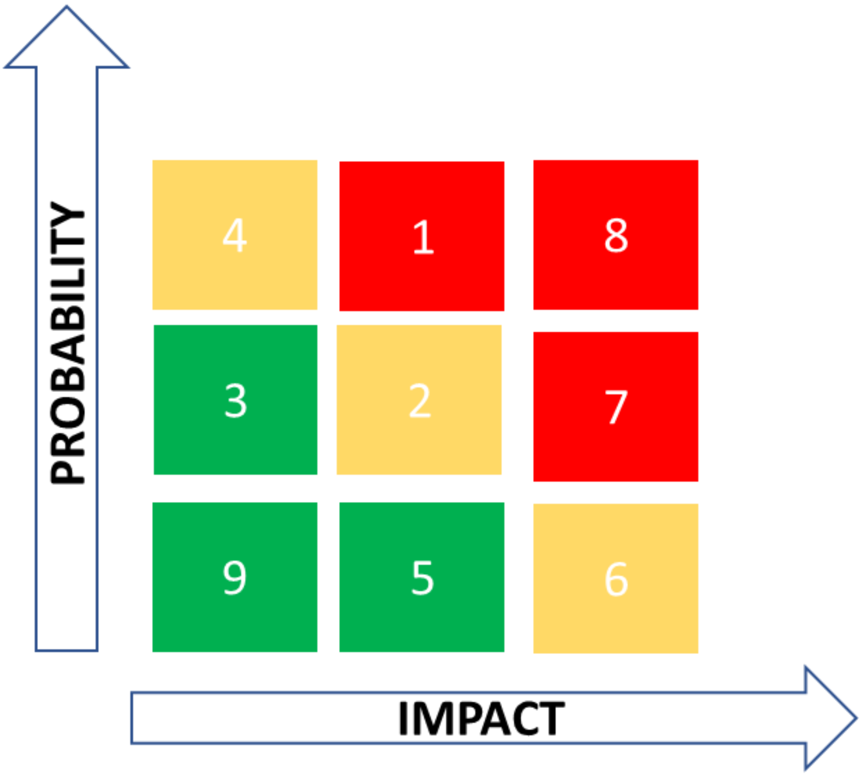


Fig. 31. Risk matrix based on probability and impact

As a result, it is significantly important to investigate different scenarios for leakage through snap-fit connection. This is because leakage is a major concern from the product functionality point of view. Additionally, urine collection bag contains a reflexive valve feature in order to prevent fluid leakage out of the bag. Then, raw material geometry must be carefully reviewed, and the state of equipment re-evaluated for the process changeover. Lastly, it is inevitable that lack of employee skills impacts negatively to process efficiency, however, throughout the period of time people tend to increase their productivity while gaining more experience.

3.3.2. Comparison of Different Tubing Process

Although rotary friction welding is a sophisticated and well-known process in company "X", it causes additional costs due to occasional poor product quality. The mechanical joint process is more reliable because it eliminates defects that are particularly important to the user. The removed defects are:

- Flashes on outer product surfaces,
- Swarfs inside urine collection bag,
- Narrow weld seam.

The particles that are outside the product but still attached from welding zone can be dangerous to consumers. There is a risk that a plastic fragment can get inside the human body while inserting catheters in urinary track and it may cause urinal infection. Moreover, plastics chips that can be found inside the urine collection bag may appear after rotary friction welding. It does not arise a risk for human safety, however, such particles can mislead customers health condition. In some cases, patients or clinical workers evaluate the content of the bag. Therefore, found particles can scare the client because it may appear in the bag from their body. Lastly, due to narrow weld there is a risk that connection does not withstand the content of the filled bag and come loose, whereas customers can be filled with the content from the bag.

Additionally, tension testing is applied to evaluate the strength of the bond between catheter and urine bag. The same test method can be used for both processes: snap-fit and welding. It is performed, when upper grippers clamp the bag port and lower ones grab the catheter tube. After clamping, tension force is applied, while stretching the bond between grippers. It is required to withstand 20 N for both types of connections. This value is needed to hold one litre bag volume with additional safety coefficients.

30 samples were taken for both process tension testing and Results are presented in tables below (Table 7; Table 8). It is proved that connection strength is no less than 20 N for both types of assembly, therefore, it complies the requirements of quality control. Moreover, on the average bond strength for rotary friction welding reaches 218 N, however, average snap-fit bond strength is half the value of old process – around 110 N. What is more, the welding seam had a maximum resistance of 235.4 N and minimum of 190.3 N, where the amplitude is around 45 N. In comparison, mechanical coupling withstood the maximum value of 128.2 N and the lowest value of 93.7 N, where amplitude is 34.5 N. It is readily perceived that strength of rotary friction weld is two times stronger rather than snap-fit joint.

Moreover, scatter diagrams were created to compare the distribution of values for bond strength for both processes (Fig. 32, Fig. 33). The distribution of the data is relatively even, linear trends can be noticed and there are no significant deviations from the average of bond strength values. According to the quality standards in company "X", there is no requirement that the connection should withstand the highest possible tension, it is allowed to reach at least 20 N limit. Therefore, even though the results of alternative tubing solutions are lower twice compared to old assembly, nevertheless it is acceptable from the product quality point view.

Table 7. Tension testing results for rotary friction welding process

Test	Defect characteristic	Quantity Inspected Fail / Total	Process
Bond strength	**>20N**	**0/30**	**Rotary friction welding**
Sample #	**Result, N**	**Sample #**	**Result, N**
1	190.3	16	227.1
2	201.5	17	216.2
3	222.5	18	223.1
4	211.9	19	228.4
5	203.1	20	220.6
6	195.9	21	233.1
7	216.4	22	209.3
8	201.2	23	215.4
9	208.8	24	213.5
10	218.7	25	230.1
11	217.7	26	232.6
12	220.6	27	211.8
13	220.5	28	212.6
14	229.9	29	233.6
15	235.4	30	231.3

Table 8. Tension testing results for snap-fit

Test	Defect characteristic	Quantity Inspected Fail / Total	Process
Bond strength	**>20N**	**0/30**	**Snap-fit**
Sample #	**Result, N**	**Sample #**	**Result, N**
1	93.7	16	120.6
2	101.9	17	99.2
3	104.3	18	111.9
4	99.4	19	109.5
5	99.1	20	110.1
6	114.2	21	127.8
7	101.1	22	112.2
8	108.1	23	124.4
9	100.3	24	116.3
10	101.5	25	115.2
11	99.3	26	120.8
12	104.4	27	128.2
13	102.6	28	123.7
14	108.2	29	120.2
15	112.7	30	110.1

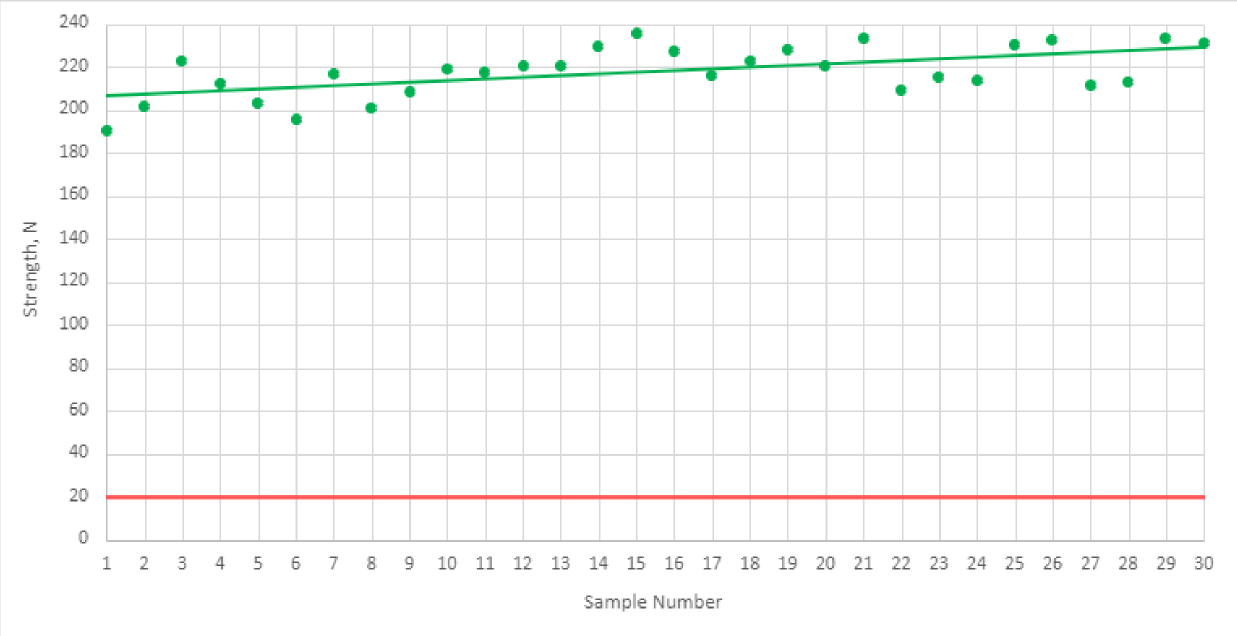


Fig. 32. Scatter diagram of bond strength results for rotary friction welding

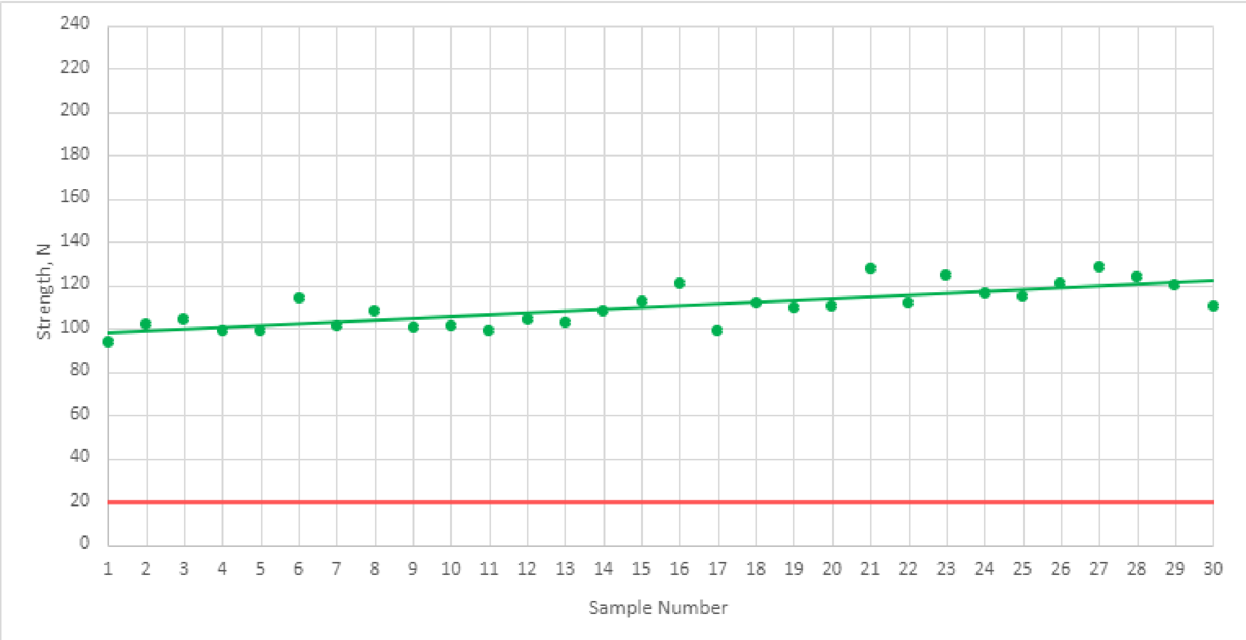


Fig. 33. Scatter diagram of bond strength results for snap-fit

What is more, it is an advantage that there is an opportunity to increase the production capacity simply by modifying the equipment parts and the software program. On the other hand, launching a new process, difficulties may arise, while employees are fully trained and maintaining loyal clients due to the changed product design. Comparison summary is presented in Table 9.

Table 9. Tubing process comparison

Criteria	Rotary friction welding	Snap-fit
Potential defects relating to assembly process	Narrow weld Excess material out of seam (flash, swarf)	Damaged connection
Process reliance	Old, well-known process; Highly rely on manual labour	New, not enough data to evaluate reliability
Average bond strength	217 N	110 N
Equipment efficiency	Advisable 10 ppm, on average 80% OEE	Manageable 11 ppm, not enough data to evaluate OEE
Equipment complexity	Semi-automatic machine, mechanical changes trigger defect peaks	The same machine, no triggers noticed, longer process changeover time
Employee skills	All personnel are trained, Easy to learn	New process, Additional time needed to present new product and train workers

Overall, when choosing an alternative tubing solution, it is necessary to evaluate not only the design of components, the adaptation of equipment or the creation of new ones, but also the company's strategic plans for the launch of a new product on the market. The mechanical connection meets the quality requirements and reduces the risks to the customers dissatisfaction due to eliminated defects. This is not only an advantage for the customer, but also for the production personnel, as it reduces downtime for product defect repair.

3.4. Summary of A3 Application and Tubing Solution

Structured problem solving is an important part of continuous improvement, and in company "X" a semi-automatic machine is used to assemble a urine collection bag and catheter. An investigation was conducted to analyse the tubing process using polyvinylchloride (PVC) tubes. The A3 Report tool is used to determine the severity, occurrence, and control of a problem, based on DMAIC (Define – Measure – Analysis – Improve – Control) method. Is/Is Not Analysis and Root Cause analysis are essential for problem solving, and A3 Report – Product Weld Width Deviation was conducted to identify the primary cause. Weld deterioration accounts for 10% of additional cost rate when weld width does not match product standard requirements, resulting in 10,000 parts manufactured and 100 units rejected. The A3 research aims to identify the primary problem and eliminate or reduce 0.5% defects of weld width lower than 2 millimetres by April 2023. Root cause analysis is conducted using the 6M technique and four main factors are identified: mechanical part wear, part installation, quality of raw material, and manual bag folding. Mechanical units, accuracy of components installation, and deformation of PVC are all important factors in welding quality. Oval tubes are the most common cause of narrow welds, and supplier must be informed, and remedial actions taken. Automated bag folding machines are the best approach to stop human error due to operator fatigue and slick bag surface. Countermeasures were implemented to improve mechanical aspects, product functionality, and quality concerns. Company "X" is taking measures to improve the assembly process for connecting catheter and urine collection bag tubes using snap fit, which requires changes in design, raw material geometry, equipment parts, and software. Company "X" developed a snap-fit assembly line with rotary friction welding machine, servo drives, and bag tube rim to ensure tight clamping of catheter and collection bag during insertion. Marketing team must prepare loyal customers for product changes, set a strategy for product transition, and use suitable equipment to perform both processes.

Rotary friction welding reduces product production cycle time and increases quantity of produced units per shift by 10%. FMEA is used to detect potential flaws in design. It is important to prioritize risks based on their possibility to occur and seriousness, investigate scenarios for leakage, review raw material geometry, and re-evaluate process efficiency. Comparison of different tubing processes is recommended. Rotary friction welding is two times stronger than snap-fit joints, with an average bond strength of 218 N. The mechanical connection meets the quality requirements and reduces the risks to customers dissatisfaction due to eliminated defects, which is an advantage for both customers and production personnel.

4. Evaluation of Financial Benefit after Improvements

It is inevitable to estimate financial value of every aspect in the business. Process changes can result in greater production and efficiency, which can directly affect the bottom line. You may gauge the success of the modifications made and pinpoint areas that still need work by analysing the financial gains of these enhancements. Overall, it is crucial to assess the financial advantages of process enhancements in order to comprehend how these adjustments will affect the organization's bottom line and make wise choices regarding additional expenditures and advancements.

4.1. Cost Saving After A3

Data of waste rate was collected before investigating the causes of narrow weld appearance (Table 10). Data is summarized in weekly manner from Week 46 2022 till Week 1 2023. It can be seen that quantity of narrow weld consists of the greatest part of all listed defects (from 210 to 1477 units weekly). Comparing to collected data after structured problem-solving investigation (Table 11) significant changes can be noticed. For example, research team were able to reduce the number of narrow weld by 20 times after implementing countermeasures.

Table 10. Data on scrap rate before A3 research

Defect types:	**Wk46**	**Wk47**	**Wk48**	**Wk49**	**Wk50**	**Wk1**
	Units per week					
Narrow weld	210	315	427	707	1204	1477
Product dropped on the floor	7	0	14	0	0	7
Channels in the weld zone	28	7	42	14	14	28
Damaged assembly	7	28	14	7	42	98
Damaged bag	21	14	7	21	28	77
Damaged catheter	14	14	0	7	35	7
Particulate contaminate	7	7	14	0	7	7
Flash	28	42	49	0	28	91
Swarf	42	7	0	7	14	42
QA destructive sample	112	112	112	112	112	112
Calculations:						
Total number of defects:	476	546	679	875	1484	1946
Total units produced:	70476	70546	70679	70875	71484	71946
Yield, %:	99.32	99.23	99.04	98.77	97.92	97.30
Overall waste, %:	0.68	0.77	0.96	1.23	2.08	2.70
Narrow weld % out of overall:	0.44	0.58	0.63	0.81	0.81	0.76

Table 11. Data of scrap rate after A3 research

Defect types:	Wk12	Wk13	Wk14	Wk15	Wk16	Wk17
	Units per week					
Narrow weld	35	31	27	55	40	14
Product dropped on the floor	6	1	3	0	2	7
Channels in the weld zone	7	4	4	14	2	2
Damaged assembly	3	5	4	7	6	10
Damaged bag	5	2	0	21	10	8
Damaged catheter	6	7	1	7	5	7
Particulate contaminate	8	3	6	0	4	2
Flash	14	10	18	0	5	60
Swarf	12	7	2	7	4	1
QA destructive sample	112	112	112	112	112	112
Calculations:						
Total number of defects:	208	182	177	223	190	223
Total units produced:	70208	70182	70177	70223	70190	70223
Yield, %:	99.70	99.74	99.75	99.68	99.73	99.68
Overall waste, %:	0.30	0.26	0.25	0.32	0.27	0.32
Narrow weld % out of overall:	0.17	0.17	0.15	0.25	0.21	0.06

However, gathering data is important for a number of reasons. For instance, it offers the data required to reach logical conclusions. Organizations can evaluate development over time, pinpoint areas for improvement, and establish improvement targets by gathering data on performance indicators. Additionally, firms can find patterns and trends in consumer behaviour, market trends, and operational performance through data collection and analysis, which can help them make decisions.

Furthermore, the calculations were made to assess additional waste-related costs incurred before and after A3 research (Table 13, Table 14). The cost of the material or component was multiplied by the quantity of defects as the calculating technique. For instance, the average cost per unit for the defects that were compound-damaged was EUR 1.7. The unit cost is typically 1.13 EUR and the folded bag is 0.33 EUR when only the catheters are affected (Table 12).

Table 12. Cost of products in production

Product	Unit price, EUR	Average, EUR
Assembly	1.38-2.69	1.70
Catheter	0.82-2.12	1.13
Urine Collection Bag	0.17	
Folded Urine Collection Bag	0.33	

Table 13. Expenses associated with waste prior to A3 investigation

Defect types:	Wk46	Wk47	Wk48	Wk49	Wk50	Wk1	Total sum per 6 weeks:
	Cost per week, EUR						
Narrow weld	357.00	535.50	725.90	1201.90	2046.80	2510.90	**7378.00**
Product dropped on the floor	11.90	0.00	23.80	0.00	0.00	11.90	
Channels in the weld zone	47.60	11.90	71.40	23.80	23.80	47.60	
Damaged assembly	11.90	47.60	23.80	11.90	71.40	166.60	
Damaged bag	6.93	4.62	2.31	6.93	9.24	25.41	
Damaged catheter	15.82	15.82	0.00	7.91	39.55	7.91	
Particulate contaminate	11.90	11.90	23.80	0.00	11.90	11.90	
Flash	47.60	71.40	83.30	0.00	47.60	154.70	
Swarf	71.40	11.90	0.00	11.90	23.80	71.40	**Total sum per 6 weeks:**
QA destructive sample	190.40	190.40	190.40	190.40	190.40	190.40	
Total sum per week:	772.45	901.04	1144.71	1454.74	2464.49	3198.72	**9936.15**
NW cost out of total:	46.22%	59.43%	63.41%	82.62%	83.05%	78.50%	**74.25%**

Table 14. Cost related to reduced waste after A3 research

Defect types:	Wk46	Wk47	Wk48	Wk49	Wk50	Wk1	Total sum per 6 weeks:
	Cost per week, EUR						
Narrow weld	59.50	52.70	45.90	93.50	68.00	23.80	**343.40**
Product dropped on the floor	10.20	1.70	5.10	0.00	3.40	11.90	
Channels in the weld zone	11.90	6.80	6.80	23.80	3.40	3.40	
Damaged assembly	5.10	8.50	6.80	11.90	10.20	17.00	
Damaged bag	1.65	0.66	0.00	6.93	3.30	2.64	
Damaged catheter	6.78	7.91	1.13	7.91	5.65	7.91	
Particulate contaminate	13.60	5.10	10.20	0.00	6.80	3.40	
Flash	23.80	17.00	30.60	0.00	8.50	102.00	
Swarf	20.40	11.90	3.40	11.90	6.80	1.70	**Total sum per 6 weeks:**
QA destructive sample	190.40	190.40	190.40	190.40	190.40	190.40	
Total sum per week:	343.33	302.67	300.33	346.34	306.45	364.15	**1963.27**
NW cost out of total:	17.33%	17.41%	15.28%	27.00%	22.19%	6.54%	**17.49%**

Overall, the A3 study was successful, at least based on the favourable financial outcomes. The analysis of data collected over a period of six weeks revealed that the researchers were able to save almost 8000 EUR by reducing the amount of waste they produced each week. It is clear that there has been a significant improvement as the narrow weld percentage reduced to just 18% after development from a prior inquiry narrow weld cases comprising almost 70% of the overall fault rate.

4.2. Cost Saving After New Assembly Design

For comparing economical value for rotary friction welding and alternative tubing solution machine hourly rate (MHR) was calculated. On one hand, the same semi-automatic equipment is used for both processes, therefore, MHR should be equal. However, main difference between the calculations is maintenance cost. It is assumed that for Snap-fit assembly time needed for reactive maintenance is reduced due to decreased downtime of quality concerns.

$$MHR = \frac{S_{dep}+S_{per}+S_{ene}+S_{are}+S_{mai}+S_{tools}}{MWT} \quad , \tag{1}$$

Where: MHR is the machine hourly rate (EUR/h); S_{dep} is the cost depreciation (EUR); S_{per} is the cost of employee (EUR); S_{ene} is the cost of energy consumption (EUR); S_{are} is the cost of occupancy (EUR); S_{mai} is the maintenance cost (EUR); S_{tools} is the cost for the tooling (EUR); MWT is the machine working time (h/year).

$$S_{dep} = \frac{Procurement\ value\ (EUR)}{Service\ life\ (year)}, \tag{2}$$

$$S_{per} = Operator\ cost\ \left(\frac{EUR}{h}\right) * MWT(h/year), \tag{3}$$

$$S_{ene} = Max\ machine\ power\ (kW) * Efficiency\ (\%) * Energy\ cost\ \left(\frac{EUR}{kWh}\right) * MWT\ (h/year), \tag{4}$$

$$S_{are} = Space\ cost\ rate\ \left(\frac{EUR}{month(m^2)}\right) * 12\ months * Required\ space\ (m^2), \tag{5}$$

$$S_{mai} = \left(Preventive\ maintenance\ (h/year) + Reactive\ maintenance\ (h/year)\right) * Maintenance\ technician\ cost\ (EUR/h), \tag{6}$$

4.2.1. Machine Hourly Rate for Rotary Friction Welding Equipment

Depreciation cost is based on the machine value and service life ratio (Eq. 2). Machine price is 20000 EUR and its service life reaches 15 years.

$$S_{dep} = \frac{20000}{15} = 1333.33\ EUR$$

Employee cost consists of production workers wages (Eq. 3). Four operators are needed to operate machine a regular production goes 24 hours a day, 7 days a week. It is decided to evaluate 340 days out of 1 year period due to scheduled annual leaves in winter and summer.

$$S_{per} = 4 * 14 * 24 * 340 = 456960\ EUR$$

Multiplying machine power, equipment efficiency, energy cost and machine working time, energy cost can be calculated (Eq. 4).). Machine power is around 25kW and electricity cost about 0.1 EUR in industries.

$$S_{ene} = 25.2 * 0.8 * 0.1 * 340 * 24 = 1451.52\ EUR$$

The machine occupy 3.3 m^2, therefore, occupancy cost is close to 200 EUR (Eq. 5).

$$S_{are} = 5 * 12 * (1.5 * 2.2) = 198\ EUR$$

Preventive and Reactive actions are included in maintenance cost (Eq. 6). Preventive maintenance consists of weekly, monthly, quarterly and annual tasks and on average takes 22 hours per one year. Reactive maintenance is based on fixing quality concerns and machine errors.

$$S_{mai} = (22 + 340) * 16 = 5792\ EUR$$

For tooling it is required to replace the knives weekly and worn machine parts occasionally.

$$S_{tools} = 20 * 48 + 1000 = 1960\ EUR$$

Taking everything into consideration, machine hourly rate (Eq. 1) reaches 57.32 EUR/h for rotary friction welding.

$$MHR = \frac{1333.33 + 456960 + 1451.52 + 198 + 5792 + 1960}{24 * 340} = 57.32\ EUR/h$$

4.2.2. Machine Hourly Rate for Snap-Fit Machine

In comparison, Snap-fit assembly machine depreciation cost is higher than welding one because of the equipment upgrade. In addition to machine price, 5000 EUR are added to cover software program changes and new machine parts.

$$S_{dep} = \frac{20000 + 5000}{15} = 1666.67\ EUR$$

What is more, personnel, consumed energy, occupancy and tooling cost remain the same, there are no radical changes to impact expenses (Table 15). On the other hand, reactive maintenance cost is considered 50% less than in previous calculations.

$$S_{mai} = (22 + 170) * 16 = 3072\ EUR$$

To sum up, machine hourly rate for Snap-fit is slightly lower than welding one – 57.02 EUR/h. This is due to lower maintenance costs.

$$MHR = \frac{2300 + 456960 + 1451.52 + 198 + 3072 + 1960}{24 * 340} = 57.02\ EUR/h$$

Table 15. Cost comparison between old and new tubing solutions

	Rotary Friction Welding	Snap-Fit
Depreciation cost, EUR	1333.33	1666.67
Employee cost, EUR	456,960.00	
Energy cost, EUR	1451.52	
Occupancy cost, EUR	198.00	
Maintenance cost, EUR	5792.00	3072.00
Tooling cost, EUR	1960	
MHR, EUR/h	57.32	57.02
Parts per minute	10	11
Unit target per 24 hours	10000	11000

	Rotary Friction Welding	Snap-Fit
Average parts per hour	417	458
Material cost, EUR/h	708.33	870.83
Production cost, EUR/h	40,601.67	49,654.92
Profit, EUR/h	4872.20	5958.59
Production cost, EUR/year	331,309,600.00	405,184,120.00
Profit, EUR/year	39,757,152.00	48,622,094.40

Overall, after the machine modifications, it is able to perform 11 parts per minute instead of 10, thus, increasing the production capacity. It is estimated that profit is generated 12% from the cost of production. Therefore, it is forecasted that Snap-fit brings around 48 million EUR profit per year, which is 8,9 million EUR more compared to profit made with rotary friction welding (Table 15).

4.3. Summary of Economical Evaluation

It is important to assess the financial benefits of process enhancements to understand how they will affect the bottom line and make wise decisions. Data collection and analysis are important for evaluating development, pinpointing areas for improvement, and establishing improvement targets. The A3 study was successful in saving 8000 EUR by reducing waste and narrowing the weld percentage. Maintenance cost was reduced due to decreased downtime of quality concerns. Machine hourly rate was calculated to compare economical value. Snap-fit assembly machine depreciation cost is higher than welding one due to equipment upgrade, while reactive maintenance cost is 50% less. Machine hourly rate is slightly lower than welding one due to lower maintenance costs, resulting in 48 million EUR profit per year.

Conclusions

1. Tube connections can be accomplished through a variety of welding techniques, adhesive bonding, and mechanical connections. Advantages and disadvantages, suitability of welding methods for materials and purposes corresponding to company's "X" products have been determined. Moreover, rotary friction welding is used for manufacturing catheter and urine collection bag assemblies in company "X".
2. Erosion, cracking, and wall thinning have been identified as welding drawbacks that contribute to pipeline failure. Lack of sufficient tightness between cylindrical surfaces is a negative aspect of mechanical bond. Nevertheless, company "X" faced various challenges regarding rotary friction welding, which caused on average 1.4% overall waste.
3. A3 report was used to investigate tubing process concerns in company "X". Situation analysis led to research target of decreasing narrow weld defect rate below 0.5%. As a result of cause and effect analysis, mechanical part wear and installation, raw material quality and manual labour have been identified as potential root causes. After implemented countermeasures narrow weld defect rate was reduced from 0.67% to 0.17% of overall defect rate. Moreover, long term solution was implemented by joining the catheter and urine collection bag in snap-fit approach.
4. The following economic benefits of tubing process improvement have been identified: after A3 actions implementation 80% of overall waste rate was reduced, and it is estimated that employing the snap-fit method rather than rotary friction welding will result in an increase in annual revenue of 8,9 million EUR. Investigation revealed that in 6 weeks duration 7378 EUR were spent due to quantity of narrow weld and 9936.15 EUR including total waste rate prior A3 investigation. What is more, 7034.60 EUR were saved reducing narrow weld cases and 7972.88 EUR diminishing overall waste in 6 weeks period after A3 study.

The proposed hypothesis was confirmed by increased manufacturing output, decreased scrap rate, and manufacturing costs after applying structured problem-solving techniques to enhance the PVC tube assembly process.

List of References

1. JHA, H.K. - JACOB, D. Legitimizing a practice across fields: microprocesses of theorization of Design Thinking. In *Journal of Professions and Organization* [Online]. 2020. Vol. 7, no. 2, p. 156–187. [Accessed 2023-03-08]. Available from: https://academic.oup.com/jpo/article/7/2/156/5843508.
2. SANTOS FILHO, G.M. - SIMÃO, L.E. A3 methodology: going beyond process improvement. In *Revista de Gestao* . 2022. Vol. ahead-of-p, no. ahead-of-print. [Accessed 2022-10-02].
3. RINI, S. Implementation of lean thinking through A3 report in plastic injection company. In *International Journal of Industrial Optimization* [Online]. 2021. Vol. 2, no. 1, p. 63. [Accessed 2022-10-02]. Available from: https://www.researchgate.net/publication/349592962_Implementation_of_lean_thinking_through_A3_report_in_plastic_injection_company.
4. YÖRÜKOĞLU, K. et al. Improving histopathology laboratory productivity: Process consultancy and A3 problem solving. In *Turk Patoloji Dergisi*. 2017. Vol. 33, no. 1, p. 47–57. [Accessed 2022-10-02].
5. MYERS, J.S. et al. Development and validation of an A3 problem-solving assessment tool and self-instructional package for teachers of quality improvement in healthcare. In *BMJ Qual Saf* [Online]. 2022. Vol. 31, p. 287–296. [Accessed 2022-10-02]. Available from: http://qualitysafety.bmj.com/.
6. FURTERER, S.L. Applying Lean Six Sigma methods to reduce length of stay in a hospital's emergency department. In *https://doi.org/10.1080/08982112.2018.1464657* [Online]. 2018. Vol. 30, no. 3, p. 389–404. [Accessed 2023-04-15]. Available from: https://www.tandfonline.com/doi/abs/10.1080/08982112.2018.1464657.
7. OWAD, A. AL et al. An integrated lean methodology for improving patient flow in an emergency department–case study of a Saudi Arabian hospital. In *Production Planning and Control*. 2018. Vol. 29, no. 13, p. 1058–1081. [Accessed 2023-04-15].
8. ALVES, A.C. Use of A3 Report by Industrial Engineering Students As a Tool to Analyze and Interpret a Case Study. In *ASME International Mechanical Engineering Congress and Exposition, Proceedings (IMECE)*. 2021. Vol. 9. [Accessed 2022-10-02].
9. YULIATI, L. et al. Problem Solving Skills on Direct Current Electricity through Inquiry-Based Learning with PhET Simulations. In *International Journal of Instruction* [Online]. 2018. Vol. 11, no. 4, p. 123–138. [Accessed 2023-04-16]. Available from: www.e-iji.net.
10. LENORT, R. et al. A3 Method as a Powerful Tool for Searching and Implementing Green Innovations in an Industrial Company Transport. In *Procedia Engineering*. 2017. Vol. 192, p. 533–538. [Accessed 2022-10-02].
11. E. ILORI, A. et al. Application of Cause-and-Effect-Analysis for Evaluating Causes of Fire Disasters in Public and Private Secondary Schools in Ilorin Metropolis, Nigeria. In *Archives of Current Research International*. 2020. p. 1–11. [Accessed 2023-04-16].
12. TORTORELLA, G. et al. Hoshin Kanri and A3: a proposal for integrating variability into the policy deployment process. In *TQM Journal*. 2019. Vol. 31, no. 2, p. 118–135. [Accessed 2023-04-16].
13. ONYUSHEVA, I. et al. THE US-CHINA TRADE WAR: CAUSE-EFFECT ANALYSIS. In *The EUrASEANs: journal on global socio-economic dynamics* [Online]. 2019. Vol. 1, no. 1(14),

p. 07–15. [Accessed 2023-04-16]. Available from: https://euraseans.com/index.php/journal/article/view/121.

14. MARTINSEN, K. et al. Joining of dissimilar materials. In *CIRP Annals*. 2015. Vol. 64, no. 2, p. 679–699. [Accessed 2023-04-02].
15. ABE, Y. et al. Joining of high strength steel and aluminium alloy sheets by mechanical clinching with dies for control of metal flow. In *Journal of Materials Processing Technology*. 2012. Vol. 212, no. 4, p. 884–889. [Accessed 2023-04-02].
16. KUMAR, R. et al. Weldability of thermoplastic materials for friction stir welding- A state of art review and future applications. In *Composites Part B: Engineering*. 2018. Vol. 137, p. 1–15. [Accessed 2023-04-02].
17. KAH, P. - SUORANTA, R. Techniques for joining dissimilar materials: metals and polymers. In *Review of Advanced Material Science* [Online]. 2014. Vol. 36, no. 2. [Accessed 2023-04-02]. Available from: https://www.academia.edu/13302599/Techniques_for_joining_dissimilar_materials_metals_and_polymers.
18. GAO, D. Mechanical Assembly Design Strategy for Rapid Development of Technology. In *Applied Mechanics and Materials* [Online]. 2013. Vol. 340, p. 95–99. [Accessed 2023-04-02]. Available from: https://www.scientific.net/AMM.340.95.
19. MATHIESON, J.L. et al. Assembly time modelling through connective complexity metrics. In *https://doi.org/10.1080/0951192X.2012.684706* [Online]. 2013. Vol. 26, no. 10, p. 955–967. [Accessed 2023-04-02]. Available from: https://www.tandfonline.com/doi/abs/10.1080/0951192X.2012.684706.
20. RD, A. *Adhesive Bonding: Science, Technology and Applications*. Sud. Adams RD. [s.l.]: Woodhead Publishing Limited, 2021. 1–826 p. ISBN 9780323851435.
21. BANEA, M.D. et al. Principles of Adhesive Bonding. In *Joining of Polymer-Metal Hybrid Structures: Principles and Applications* [Online]. 2018. p. 3–27. [Accessed 2023-04-02]. Available from: https://onlinelibrary.wiley.com/doi/full/10.1002/9781119429807.ch1.
22. REYES, G. et al. Solvent Welding and Imprinting Cellulose Nanofiber Films Using Ionic Liquids. In *Biomacromolecules* [Online]. 2019. Vol. 20, no. 1, p. 502–514. [Accessed 2023-04-02]. Available from: https://pubs.acs.org/doi/full/10.1021/acs.biomac.8b01554.
23. HARRIS, C.M. *Dictionary of architecture & construction / edited by Cyril M. Harris.* [Online]. 4. Ed. [s.l.]: New York : McGraw-Hill, c2006., 2006. ISBN 0071452370.
24. POURANVARI, M. - MARASHI, S.P.H. Critical review of automotive steels spot welding: process, structure and properties. In *http://dx.doi.org/10.1179/1362171813Y.0000000120* [Online]. 2013. Vol. 18, no. 5, p. 361–403. [Accessed 2023-04-02]. Available from: https://www.tandfonline.com/doi/abs/10.1179/1362171813Y.0000000120.
25. GONG, H. et al. Review of research on loosening of threaded fasteners. In *Friction* [Online]. 2022. Vol. 10, no. 3, p. 335–359. [Accessed 2023-04-02]. Available from: https://link.springer.com/article/10.1007/s40544-021-0497-1.
26. DETZEL, S. et al. Mechanical Properties of Snap-Fits Fabricated by Selective Laser Sintering From Polyamide. In *ASME International Mechanical Engineering Congress and Exposition, Proceedings (IMECE)* [Online]. 2022. Vol. 3. [Accessed 2023-04-02]. Available from: /IMECE/proceedings-abstract/IMECE2021/85574/1132547.

27. SUN, J. et al. Study on the Design Method of Ring Groove Rivet Joint in Aluminum Alloy Structure. In *International Journal of Steel Structures* [Online]. 2022. Vol. 22, no. 1, p. 294–307. [Accessed 2023-04-02]. Available from: https://link.springer.com/article/10.1007/s13296-021-00575-x.
28. HAQ, M. - DRZAL, L.T. Active, tailorable adhesives for dissimilar material bonding, repair and reassembly. In [Online]. 2019. [Accessed 2023-04-02]. Available from: http://www.osti.gov/servlets/purl/1497730/.
29. MESKO, J. - ET AL Microstructure analysis of welded joints after laser welding. In *Manufacturing Technology* [Online]. 2014. Vol. 14, no. 3, p. 355–359. [Accessed 2023-04-02]. Available from: https://www.researchgate.net/publication/281663531.
30. JEEVI, G. et al. Review on adhesive joints and their application in hybrid composite structures. In *https://doi.org/10.1080/01694243.2018.1543528* [Online]. 2019. Vol. 33, no. 14, p. 1497–1520. [Accessed 2023-04-03]. Available from: https://www.tandfonline.com/doi/abs/10.1080/01694243.2018.1543528.
31. CARBAS, R.J.C. et al. Adhesively bonded functionally graded joints by induction heating. In *International Journal of Adhesion and Adhesives*. 2014. Vol. 48, p. 110–118. [Accessed 2023-04-03].
32. BODJONA, K. et al. Load sharing in single-lap bonded/bolted composite joints. Part I: Model development and validation. In *Composite Structures*. 2015. Vol. 129, p. 268–275. [Accessed 2023-04-03].
33. WANG, B. et al. Improvement of adhesive bonding of grit-blasted steel substrates by using diluted resin as a primer. In *International Journal of Adhesion and Adhesives*. 2017. Vol. 73, p. 92–99. [Accessed 2023-04-12].
34. LEE, H. et al. Effect of plasma surface treatment of recycled carbon fiber on carbon fiber-reinforced plastics (CFRP) interfacial properties. In *Applied Surface Science*. 2015. Vol. 328, p. 241–246. [Accessed 2023-04-12].
35. RAUH, B. et al. UV-laser cleaning and surface characterization of an aerospace carbon fibre reinforced polymer. In *International Journal of Adhesion and Adhesives*. 2018. Vol. 82, p. 50–59. [Accessed 2023-04-12].
36. SRIVASTAVA, M. et al. Potential of Using Water Jet Peening as a Surface Treatment Process for Welded Joints. In *Procedia Engineering*. 2016. Vol. 149, p. 472–480. [Accessed 2023-04-12].
37. BUDHATHOKI, S.S. et al. Awareness of occupational hazards and use of safety measures among welders: a cross-sectional study from eastern Nepal. In *BMJ Open* [Online]. 2014. Vol. 4, no. 6. [Accessed 2023-04-13]. Available from: https://bmjopen.bmj.com/content/4/6/e004646.
38. STENBERG, T. et al. Quality control and assurance in fabrication of welded structures subjected to fatigue loading. In *Welding in the World* [Online]. 2017. Vol. 61, no. 5, p. 1003–1015. [Accessed 2023-04-13]. Available from: https://link.springer.com/article/10.1007/s40194-017-0490-5.
39. GIBSON, B.T. et al. Friction stir welding: Process, automation, and control. In *Journal of Manufacturing Processes*. 2014. Vol. 16, no. 1, p. 56–73. [Accessed 2023-04-12].
40. SHETE, N. - DEOKAR, S.U. A Review Paper on Rotary Friction Welding. In *International Conference on Ideas, Impact and Innovation in Mechanical Engineering* [Online]. 2017. p. 1557–1560. [Accessed 2023-04-12]. Available from: http://www.ijritcc.org.

41. GROOVER, M.P. *Fundamentals of modern manufacturing: materials, processes, and systems* [Online]. 4th. Ed. [s.l.]: J. Wiley & Sons, 2010. ISBN 0470467002.
42. LI, W. et al. Linear and rotary friction welding review. In *http://dx.doi.org/10.1080/09506608.2015.1109214* [Online]. 2016. Vol. 61, no. 2, p. 71–100. [Accessed 2023-04-12]. Available from: https://www.tandfonline.com/doi/abs/10.1080/09506608.2015.1109214.
43. VAIRIS, A. - FROST, M. Modelling the linear friction welding of titanium blocks. In *Materials Science and Engineering: A*. 2000. Vol. 292, no. 1, p. 8–17. [Accessed 2023-04-12].
44. VAIRIS, A. - FROST, M. On the extrusion stage of linear friction welding of Ti 6Al 4V. In *Materials Science and Engineering: A*. 1999. Vol. 271, no. 1–2, p. 477–484. [Accessed 2023-04-12].
45. DARMADI, D.B. - TALICE, M. Improving the strength of friction stir welded joint by double side friction welding and varying pin geometry. In *Engineering Science and Technology, an International Journal* [Online]. 2021. Vol. 24, no. 3, p. 637–647. [Accessed 2023-04-12]. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2215098620342397.
46. RAAB, U. et al. Orbital friction welding as an alternative process for blisk manufacturing. In *Journal of Materials Processing Technology*. 2015. Vol. 215, no. 1, p. 189–192. [Accessed 2023-04-12].
47. MAALEKIAN, M. - CERJAK, H. Modelling the orbital friction welding of pearlitic steel bars. In *ASM Proceedings of the International Conference: Trends in Welding Research* [Online]. 2009. p. 736–741. [Accessed 2023-04-12]. Available from: https://www.researchgate.net/publication/228382593_Modelling_the_Orbital_Friction_Welding_of_Pearlitic_Steel_Bars.
48. MURPHY, A.B. A Perspective on Arc Welding Research: The Importance of the Arc, Unresolved Questions and Future Directions. In *Plasma Chemistry and Plasma Processing* [Online]. 2015. Vol. 35, no. 3, p. 471–489. [Accessed 2023-04-13]. Available from: https://link.springer.com/article/10.1007/s11090-015-9620-2.
49. K SRIVASTAVA, A. - SHARMA, A. Advances in Joining and Welding Technologies for Automotive and Electronic Applications. In *American Journal of Materials Engineering and Technology* [Online]. 2017. Vol. 5, no. 1, p. 7–13. [Accessed 2023-04-13]. . Available from: https://www.researchgate.net/publication/319199525_Advances_in_Joining_and_Welding_Technologies_for_Automotive_and_Electronic_Applications.
50. POURANVARI, M. - MARASHI, S.P.H. Critical review of automotive steels spot welding: process, structure and properties. In *http://dx.doi.org/10.1179/1362171813Y.0000000120* [Online]. 2013. Vol. 18, no. 5, p. 361–403. [Accessed 2023-04-13]. Available from: https://www.tandfonline.com/doi/abs/10.1179/1362171813Y.0000000120.
51. KOCSIS, B. et al. Investigation of the Effects of Thermit Welding on the Mechanical Properties of the Rails. In *Acta Polytechnica Hungarica* [Online]. 2022. Vol. 19, no. 3, p. 37–49. [Accessed 2023-04-13]. Available from: https://www.researchgate.net/publication/355734459.
52. Cambridge Dictionary | English Dictionary, Translations & Thesaurus. In [Online]. [Accessed 2023-04-16]. Available from: https://dictionary.cambridge.org/.
53. KAPIL, A. - SHARMA, A. Magnetic pulse welding: an efficient and environmentally friendly multi-material joining technique. In *Journal of Cleaner Production*. 2015. Vol. 100, p. 35–58. [Accessed 2023-04-16].

54. SHARMA, S.K. - MAHESHWARI, S. A review on welding of high strength oil and gas pipeline steels. In *Journal of Natural Gas Science and Engineering*. 2017. Vol. 38, p. 203–217. [Accessed 2023-04-17].
55. CUI, J. et al. Joining of tubular carbon fiber-reinforced plastic/aluminum by magnetic pulse welding. In *Journal of Materials Processing Technology*. 2019. Vol. 264, p. 273–282. [Accessed 2023-04-17].
56. SENTHIL, S.M. et al. A multi-objective optimization of the friction stir welding process using RSM-based-desirability function approach for joining aluminum alloy 6063-T6 pipes. In *Structural and Multidisciplinary Optimization* [Online]. 2020. Vol. 62, no. 3, p. 1117–1133. [Accessed 2023-04-17]. Available from: https://link.springer.com/article/10.1007/s00158-020-02542-2.
57. FARAG, M.H. - MAHDI, E. New approach of pipelines joining using fiber reinforced plastics composites. In *Composite Structures*. 2019. Vol. 228. [Accessed 2023-04-17].
58. BURENIN, A.A. et al. On the modeling of the shrink fit technology. In *Journal of Applied and Industrial Mathematics*. 2014. Vol. 8, no. 4, p. 493–499. [Accessed 2023-04-17].
59. ZHANG, Q. et al. Tube/tube joining technology by using rotary swaging forming method. In *Journal of Materials Processing Technology*. 2014. Vol. 214, no. 10, p. 2085–2094. [Accessed 2023-04-17].
60. MORI, K. ichiro - ABE, Y. A review on mechanical joining of aluminium and high strength steel sheets by plastic deformation. In *International Journal of Lightweight Materials and Manufacture*. 2018. Vol. 1, no. 1, p. 1–11. [Accessed 2023-04-17].
61. WITOLD VICTOR, T. *PVC Plastics: Properties, Processing and Applications* [Online]. [s.l.]: Elsevier Science Publishers LTD, 1990. ISBN 1-85166-471-8.
62. MAST, J. DE - LOKKERBOL, J. An analysis of the Six Sigma DMAIC method from the perspective of problem solving. In *International Journal of Production Economics*. 2012. Vol. 139, no. 2, p. 604–614. [Accessed 2022-12-19].
63. COCCIA, M. the Fishbone diagram to identify, systematize and analyze the sources of general purpose technologies. In *Journal of Social and Administrative Sciences* [Online]. 2018. Vol. 4, no. 4, p. 291–303. [Accessed 2022-12-19]. Available from: https://ssrn.com/abstract=3100011Electroniccopyavailableat:https://ssrn.com/abstract=3100011 Electroniccopyavailableat:https://ssrn.com/abstract=3100011.
64. Toyota A3 Report | A3 Report Template in Excel. In [Online]. [Accessed 2022-10-02]. Available from: https://www.qimacros.com/quality-tools/toyota-a3-report-template/.
65. Overview of materials for PVC, Rigid Grade. In [Online]. [Accessed 2023-05-03]. Available from: https://www.matweb.com/search/datasheet_print.aspx?matguid=69642362cb864d25b8f6eb9d02092ecf.

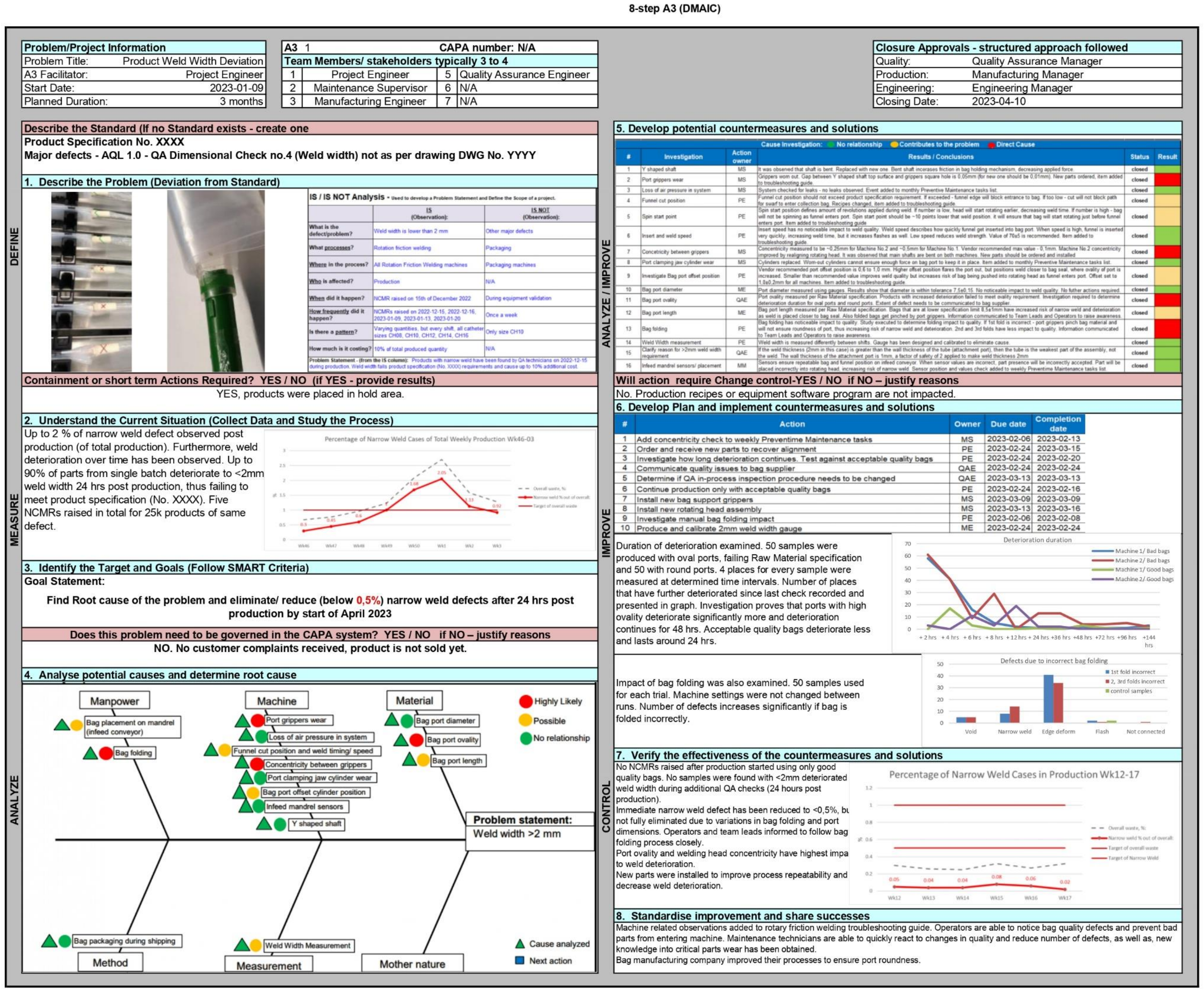
Appendices

Appendix 1. Polyvinylchloride (PVC) material various properties [65]

Properties	Metric	Comments
Physical Properties		
Density	1.16-1.65 g/cc	Average value: 1.39 g/cc Grade Count: 505
Filler Content	10.0-20.0 %	Average value: 15.0% Grade Count: 14
Volatile Organic Compounds (VOC) Content	0.300-0.500 g/l	Average value: 0.314 g/l Grade Count: 14
Particle Size	63.0-250µm	Average value: 155 µm Grade Count: 14
Viscosity Test	61.0-116 cm^3/g	Average value: 93.4 cm^3/g Grade Count: 13
Thickness	3000-12000 microns	Average value: 6940 microns Grade Count: 5
Linear Mold Shrinkage	0.000500-0.0120 cm/cm	Average value: 0.00394 cm/cm Grade Count: 76
Melt Flow	3.50-54.0 g/10 min	Average value: 20.8 g/10 min Grade Count: 13
Spiral Flow	53.3-119 cm	Average value: 78.9 cm Grade Count: 55
ASTM Colour	-15.8-81.0	Average value: 17.5 Grade Count: 4
Mechanical Properties		
Hardness, Rockwell R	100-111	Average value: 104 Grade Count:24
Hardness, Shore A	76.0 - 95.0	Average value: 86.0 Grade Count:8
Hardness, Shore D	45.0 - 88.0	Average value: 80.1 Grade Count:349
Hardness, Shore C	69.0 - 90.0	Average value: 80.9 Grade Count:8
Tensile Strength, Ultimate	14.3 - 55.2 MPa	Average value: 37.0 MPa Grade Count:75
Tensile Strength, Yield	3.45 - 73.1 MPa	Average value: 45.8 MPa Grade Count:447
Elongation at Break	2.00 - 330 %	Average value: 110 % Grade Count:241
Elongation at Yield	3.10 - 6.00 %	Average value: 5.07 % Grade Count:6
Modulus of Elasticity	1.82 - 7.03 GPa	Average value: 2.77 GPa Grade Count:298
Flexural Yield Strength	50.7 - 104 MPa	Average value: 80.8 MPa Grade Count:289
Flexural Modulus	0.220 - 6.43 GPa	Average value: 2.79 GPa Grade Count:302
Izod Impact, Notched	0.160 - 14.0 J/cm	Average value: 4.39 J/cm Grade Count:434
Izod Impact, Unnotched	0.392 - 9.70 J/cm	Average value: 3.85 J/cm Grade Count:15
Izod Impact, Notched (ISO)	1.96 - 11.8 kJ/m^2	Average value: 7.36 kJ/m^2 Grade Count:4
Charpy Impact, Notched	0.250 - 1.10 J/cm^2	Average value: 0.582 J/cm^2 Grade Count:4
Dart Drop Total Energy	11.1 - 280 J/cm	Average value: 95.6 J/cm Grade Count:150
Electrical Properties		
Electrical Resistivity	2.00e+14 - 1.00e+16 ohm-cm	Average value: 3.82e+15 ohm-cm Grade Count:5
Dielectric Constant	2.98 - 8.00	Average value: 3.96 Grade Count:3
Comparative Tracking Index	600 V	Average value: 600 V Grade Count:5
Hot Wire Ignition, HWI	60.0 - 120 sec	Average value: 90.0 sec Grade Count:5
High Amp Arc Ignition, HAI	60.0 - 120 arcs	Average value: 90.0 arcs Grade Count:5
Thermal Properties		
CTE, linear	12.0 - 140 µm/m-°C	Average value: 66.2 µm/m-°C Grade Count:152
Maximum Service Temperature, Air	60.0 - 190 °C	Average value: 153 °C Grade Count:41
Deflection Temperature at 0.46 MPa (66 psi)	41.1 - 88.9 °C	Average value: 72.5 °C Grade Count:8
Deflection Temperature at 1.8 MPa (264 psi)	17.8 - 86.1 °C	Average value: 68.2 °C Grade Count:294
Vicat Softening Point	51.0 - 98.9 °C	Average value: 84.5 °C Grade Count:149

Properties	Metric	Comments
Brittleness Temperature	-28.0 - 15.0 °C	Average value: -12.9 °C Grade Count:8
UL RTI, Electrical	29.4 - 105 °C	Average value: 75.3 °C Grade Count:34
UL RTI, Mechanical with Impact	10.0 - 105 °C	Average value: 63.6 °C Grade Count:29
UL RTI, Mechanical without Impact	29.4 - 105 °C	Average value: 74.2 °C Grade Count:34
Flammability, UL94	HB - 5VA	Grade Count:105
Oxygen Index	24.0 - 52.0 %	Average value: 31.6 % Grade Count:11
Optical Properties		
Haze	4.00 - 8.00 %	Average value: 5.10 % Grade Count:10
Gloss	5.00 - 60.0 %	Average value: 28.1 % Grade Count:4
Transmission, Visible	7.50 - 90.0 %	Average value: 78.3 % Grade Count:51
Processing Properties		
Processing Temperature	150 - 221 °C	Average value: 186 °C Grade Count:63
Nozzle Temperature	180 - 185 °C	Average value: 180 °C Grade Count:24
Melt Temperature	177 - 216 °C	Average value: 195 °C Grade Count:224
Component Elements Properties		
Sulfate, SO4	0.0300 - 0.0500 %	Average value: 0.0460 % Grade Count:5

Appendix 2. A3 Report – Product Weld Width Deviation



8-step A3 (DMAIC)

Problem/Project Information	
Problem Title:	Product Weld Width Deviation
A3 Facilitator:	Project Engineer
Start Date:	2023-01-09
Planned Duration:	3 months

A3 1 CAPA number: N/A

Team Members/ stakeholders typically 3 to 4			
1	Project Engineer	5	Quality Assurance Engineer
2	Maintenance Supervisor	6	N/A
3	Manufacturing Engineer	7	N/A

Closure Approvals - structured approach followed	
Quality:	Quality Assurance Manager
Production:	Manufacturing Manager
Engineering:	Engineering Manager
Closing Date:	2023-04-10

DEFINE

Describe the Standard (If no Standard exists - create one

Product Specification No. XXXX

Major defects - AQL 1.0 - QA Dimensional Check no.4 (Weld width) not as per drawing DWG No. YYYY

1. Describe the Problem (Deviation from Standard)

IS / IS NOT Analysis - Used to develop a Problem Statement and Define the Scope of a project.

	IS (Observation):	IS NOT (Observation):
What is the defect/problem?	Weld width is lower than 2 mm	Other major defects
What processes?	Rotation friction welding	Packaging
Where in the process?	All Rotation Friction Welding machines	Packaging machines
Who is affected?	Production	N/A
When did it happen?	NCMR raised on 15th of December 2022	During equipment validation
How frequently did it happen?	NCMRs raised on 2022-12-15, 2022-12-16, 2023-01-09, 2023-01-13, 2023-01-20	Once a week
Is there a pattern?	Varying quantities, but every shift, all catheter sizes CH08, CH10, CH12, CH14, CH16	Only size CH10
How much is it costing?	10% of total produced quantity	N/A

Problem Statement - (from the IS column): Products with narrow weld have been found by QA technicians on 2022-12-15 during production. Weld width fails product specification (No. XXXX) requirements and cause up to 10% additional cost.

Containment or short term Actions Required? YES / NO (if YES - provide results)

YES, products were placed in hold area.

MEASURE

2. Understand the Current Situation (Collect Data and Study the Process)

Up to 2 % of narrow weld defect observed post production (of total production). Furthermore, weld deterioration over time has been observed. Up to 90% of parts from single batch deteriorate to <2mm weld width 24 hrs post production, thus failing to meet product specification (No. XXXX). Five NCMRs raised in total for 25k products of same defect.

Percentage of Narrow Weld Cases of Total Weekly Production Wk46-03

3. Identify the Target and Goals (Follow SMART Criteria)

Goal Statement:

Find Root cause of the problem and eliminate/ reduce (below 0,5%) narrow weld defects after 24 hrs post production by start of April 2023

Does this problem need to be governed in the CAPA system? YES / NO if NO – justify reasons

NO. No customer complaints received, product is not sold yet.

ANALYZE

4. Analyse potential causes and determine root cause

ANALYZE / IMPROVE

5. Develop potential countermeasures and solutions

Cause Investigation: No relationship / Contributes to the problem / Direct Cause

#	Investigation	Action owner	Results / Conclusions	Status
1	Y shaped shaft	MS	It was observed that shaft is bent. Replaced with new one. Bent shaft incerases friction in bag holding mechanism, decreasing applied force.	closed
2	Port grippers wear	MS	Grippers worn out. Gap between Y shaped shaft top surface and grippers square hole is 0,05mm (for new one should be 0,01mm). New parts ordered, item added to troubleshooting guide.	closed
3	Loss of air pressure in system	MS	System checked for leaks - no leaks observed. Event added to monthly Preventive Maintenance tasks list.	closed
4	Funnel cut position	PE	Funnel cut position should not exceed product specification requirement. If exceeded - funnel edge will block entrance to bag. If too low - cut will not block path for swarf to enter collection bag. Recipes changed, item added to troubleshooting guide.	closed
5	Spin start point	PE	Spin start position defines amount of revolutions applied during weld. If number is low, head will start rotating earlier, decreasing weld time. If number is high - bag will not be spinning as funnel enters port. Spin start point should be ~10 points lower that weld position. it will ensure that bag will start rotating just before funnel enters port. Item added to troubleshooting guide	closed
6	Insert and weld speed	PE	Insert speed has no noticeable impact to weld quality. Weld speed describes how quickly funnel get inserted into bag port. When speed is high, funnel is inserted very quickly, increasing weld time, but it increases flashes as well. Low speed reduces weld strength. Value of 70±5 is recommended. Item added to troubleshooting guide.	closed
7	Concetricity between grippers	MS	Concentricity measured to be ~0,25mm for Machine No.2 and ~0,5mm for Machine No.1. Vendor recommended max value - 0,1mm. Machine No.2 concentricity improved by realigning rotating head. It was observed that main shafts are bent on both machines. New parts should be ordered and installed	closed
8	Port clamping jaw cylinder wear	MS	Cylinders replaced. Worn-out cylinders cannot ensure enough force on bag port to keep it in place. Item added to monthly Preventive Maintenance tasks list.	closed
9	Investigate Bag port offset position	PE	Vendor recommended port offset position is 0,6 to 1,0 mm. Higher offset position flares the port out, but positions weld closer to bag seal, where ovality of port is increased. Smaller than recommended value improves weld quality but increases risk of bag being pushed into rotating head as funnel enters port. Offset set to 1,0±0,2mm for all machines. Item added to troubleshooting guide.	closed
10	Bag port diameter	ME	Port diameter measured using gauges. Results show that diameter is within tolerance 7,5±0,15. No noticeable impact to weld quality. No futher actions required.	closed
11	Bag port ovality	QAE	Port ovality measured per Raw Material specification. Products with increased deterioration failed to meet ovality requirement. Investigation required to determine deterioration duration for oval ports and round ports. Extent of defect needs to be communicated to bag supplier.	closed
12	Bag port length	ME	Bag port length measured per Raw Material specification. Bags that are at lower specification limit 8,5±1mm have increased risk of narrow weld and deterioration as weld is placed closer to bag seal. Also folded bags get pinched by port grippers. Information communicated to Team Leads and Operators to raise awareness.	closed
13	Bag folding	PE	Bag folding has noticeable impact to quality. Study executed to determine folding impact to quality. If 1st fold is incorrect - port grippers pinch bag material and will not ensure roundness of port, thus increasing risk of narrow weld and deterioration. 2nd and 3rd folds have less impact to quality. Information communicated to Team Leads and Operators to raise awareness.	closed
14	Weld Width measurement	PE	Weld width is measured differently between shifts. Gauge has been designed and calibrated to eliminate cause.	closed
15	Clarify reason for >2mm weld width requirement	QAE	If the weld thickness (2mm in this case) is greater than the wall thickness of the tube (attachment port), then the tube is the weakest part of the assembly, not the weld. The wall thickness of the attachment port is 1mm, a factor of safety of 2 applied to make weld thickness 2mm	closed
16	Infeed mandrel sensors/ placement	MM	Sensors ensure repeatable bag and funnel position on infeed conveyor. When sensor values are incorrect, part presence will be incorrectly accepted. Part will be placed incorrectly into rotating head, increasing risk of narrow weld. Sensor position and values check added to weekly Preventime Maintenance tasks list.	closed

Will action require Change control-YES / NO if NO – justify reasons

No. Production recipes or equipment software program are not impacted.

IMPROVE

6. Develop Plan and implement countermeasures and solutions

#	Action	Owner	Due date	Completion date
1	Add concentricity check to weekly Preventime Maintenance tasks	MS	2023-02-06	2023-02-13
2	Order and receive new parts to recover alignment	PE	2023-02-24	2023-03-15
3	Investigate how long deterioration continues. Test against acceptable quality bags	PE	2023-02-24	2023-02-20
4	Communicate quality issues to bag supplier	QAE	2023-02-24	2023-02-24
5	Determine if QA in-process inspection procedure needs to be changed	QAE	2023-03-13	2023-03-13
6	Continue production only with acceptable quality bags	PE	2023-02-24	2023-02-16
7	Install new bag support grippers	MS	2023-03-09	2023-03-09
8	Install new rotating head assembly	MS	2023-03-13	2023-03-16
9	Investigate manual bag folding impact	PE	2023-02-06	2023-02-08
10	Produce and calibrate 2mm weld width gauge	ME	2023-02-24	2023-02-24

Duration of deterioration examined. 50 samples were produced with oval ports, failing Raw Material specification and 50 with round ports. 4 places for every sample were measured at determined time intervals. Number of places that have further deteriorated since last check recorded and presented in graph. Investigation proves that ports with high ovality deteriorate significantly more and deterioration continues for 48 hrs. Acceptable quality bags deteriorate less and lasts around 24 hrs.

Deterioration duration

Impact of bag folding was also examined. 50 samples used for each trial. Machine settings were not changed between runs. Number of defects increases significantly if bag is folded incorrectly.

Defects due to incorrect bag folding

CONTROL

7. Verify the effectiveness of the countermeasures and solutions

No NCMRs raised after production started using only good quality bags. No samples were found with <2mm deteriorated weld width during additional QA checks (24 hours post production).
Immediate narrow weld defect has been reduced to <0,5%, bu not fully eliminated due to variations in bag folding and port dimensions. Operators and team leads informed to follow bag folding process closely.
Port ovality and welding head concentricity have highest impa to weld deterioration.
New parts were installed to improve process repeatability and decrease weld deterioration.

Percentage of Narrow Weld Cases in Production Wk12-17

8. Standardise improvement and share successes

Machine related observations added to rotary friction welding troubleshooting guide. Operators are able to notice bag quality defects and prevent bad parts from entering machine. Maintenance technicians are able to quickly react to changes in quality and reduce number of defects, as well as, new knowledge into critical parts wear has been obtained.
Bag manufacturing company improved their processes to ensure port roundness.