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Case study: Half automatic coating of guide wire

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Abstract

The project presented within this paper deals with the coating process for guide wires for minimal-invasive operations in the human body. In order to reach the required quality of the coating of guide wire, adaptations of the available dipping device should be made. In the first step, the description of the multiscreen-model and the concept of the ideal machine were used to clarify the task and the expectations of the company. Following that the problem was analysed by the cause-effect-chain analysis, the function analysis and the resource collection. Based on this knowledge and results gathered engineering contradictions and physical contradictions, inventive principles and separation principles were used and starting points for solutions to fulfil our demands were collected. The development steps have been worked through systematically and efficiently by using the TRIZ methodology. First of the solutions were realized successfully.

Peer-review under responsibility of scientific committee of Triz Future Conference.

Keywords: TRIZ; coating device; dipping device; guide wires

1. The desired product

The company produces medically used guide wires, which are deployed worldwide. These special guide wires are provided for minimal invasive operations and serve as a guide to reach the desired places in the human body. To prevent injuries the tips of the guide wires should be soft and flexible.

Usually a guide wire consists of a soul and a coat (tube or spring). To get a soft tip one end of the wire is cut conically. This end has to be coated with a highly flexible synthetic material (Pebax), because the thin tip of the wire could perforate tissue. This synthetic material contains Wolfram, which can be made visible by X-rays. At last the coated wire tip and the remaining part of the wire must have the same diameter. The synthetic coating must be smooth and adhere to the wire.

Up to now these medically used guide wires have been successfully produced manually. Owing to an increasing demand the production of a higher number of units is required.

2. The existing and the further developed dipping device

2.1. The existing dipping device

From the point of cost efficiency, the available semi-automatic dipping device should be used. The following pictures show this existing dipping device and the clamping device for guide wires, which have already been used for the production of another product variant for a longer time.

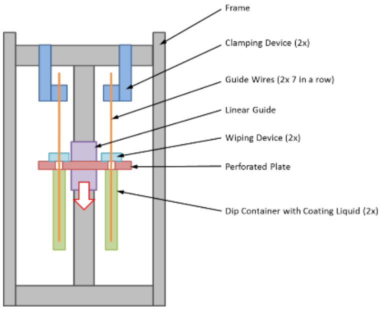

Fig. 1. Existing Dipping Device, schematic sketch.

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The clamping mechanism for the guide wire is pushed into the upper part of the installation. The 30 to 70 cm long guide wires hang down the clamping mechanism and are threaded into the perforated plate below. Underneath the perforated plate there is the narrow dip container with the coating liquid.

2.2. Description of manual coating process

During manual production, an employee dips a single wire into a bottle with coating liquid, pulls it out again and lets it dry spread out on a table for ten minutes. The speed of the movement and a little bushing within the bottle make sure that there is the desired wipe off effect of the Pebax- solution.

2.3. Description of the semi-automatic coating process

When the semi-automatic dipping device is used for this process, the guide wires are mounted into the available clamping device (2 clamping devices, each for 7 guide wires). The clamping mechanism with the wires is then inserted into the dipping device. The guide wires, hanging down from the clamping device, are then threaded into the perforated plate. Underneath the perforated plate a dip container with the coating liquid (consisting of Pebax and solvent) is moved up and down, so that the guide wires are dipped into the liquid. The bushing used for manual production cannot be applied here to wipe off excess coating liquid. Therefore a special installation for wiping off the redundant coating liquid was developed by the company.

The wiping device consists of two moveable parts with perforations and special cavitations for wiping off the coating liquid. However, the current design of the wiping device could not meet the required quality and productivity requirements, because different problems like the conglutination due to the wiped off and drying Pebax or bending of the guide wires because of imprecise threading through the holes occurred.

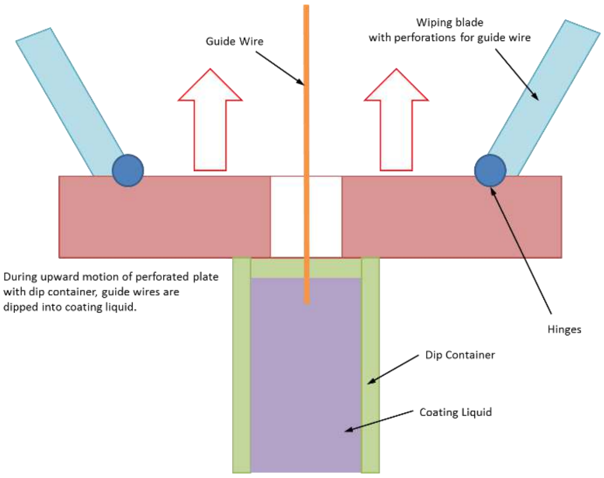

Fig. 2. Old wiping device, opened for dipping.

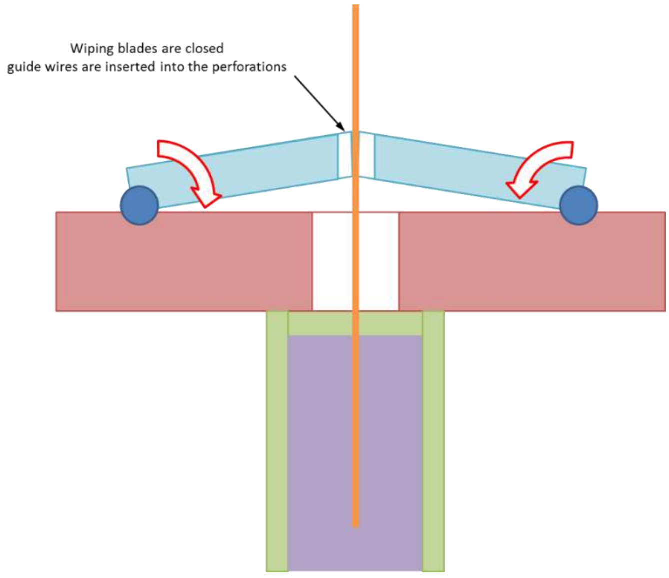

Fig. 3. Old wiping device, closed, wires threaded into perforations.

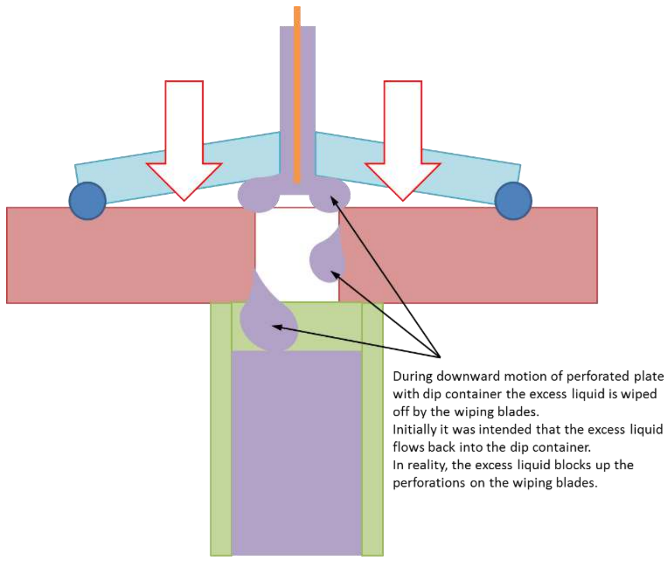

Fig. 4. Old wiping device, wiping off excess liquid

Therefore the company is currently searching for another solution for reaching an optimal quality as well as a reliable number of produced units. If it was impossible to find a qualitatively reliable and sufficiently productive mechanical solution, the guide wires would still have to be produced manually. Manual production however would raise the prize to a non-competitive level.

2.4. Allowable system changes

Because the company insists on using the available dipping device TA02, all considerations to influence or modify the working process in the supersystem have to be excluded. Nevertheless they were written down, because for an increasing demand for Pebax guide wires a new installation with a higher grade of automation is planned to be constructed.

Also, the existing clamping device for wire tips (picture 2) have to be used for the planned process. This clamping device can hold 7 wire tips and coat them all at the same time. The dipping device can take two clamping devices simultaneously. Minimal technical changes concerning the clamping device, the dip container or the linear guide are possible, and as far as they prove to be economical, they can be executed by the in-house tool shop. Additionally requirements were:

- only materials licensed for technical medicine can be used and
- the coating solution can't be changed.

2.5. Criteria for choosing solution concepts

These are the most important criteria mentioned:

- time needed for coating
- costs for converting the installation
- inhaling fumes by the employees should be prevented
- reached number of units.

2.6. Ideality

A manual coating, on the one hand, secures that the desired diameter is reached, and that redundant material is wiped off by the bushing to prevent wrinkles and drops on the dry product.

$$\text{Degree of ideality (manual process)} = \frac{\text{Even Pebax-coating (0,75mm)}}{\text{high consumption of time, consumption of material, low number of units per employee}}$$

In contrast to the current construction the realisation of the improved working process at the dipping device should include that the wiping device is supplied automatically with wires, which otherwise could not be coated. Furthermore, to avoid faults, there should only be one possible way for the wires to reach the dipping device.

$$\text{Degree of ideality (semi automatic)} = \frac{\text{Even Pebax-coating (0,75mm)}}{\text{Lower consumption of time, consumption of material distinctly higher number of units per employee, amortizing costs of investment}}$$

2.7. Ideal machine

Two aspects have to be considered concerning the demands on the ideal machine:

1. The ideal machine produces a complete coating of the guide wires in a constant quality without additional costs for cleaning after the wires have been mounted into the clamping device, which then have to be inserted into the coating device. The coating liquid has to dry quickly on the guide wires, but stay liquid in the dip container.
2. That means, at the most, the clamping devices have to be exchanged by an employee. Additionally, the clamping device by its design should allow a failure free insertion, installation and clamping of the guide wires.

At that point the clarification of the situation was sufficiently done, and the problem analysis phase started.

3. Problem analysis

The problem analysis was performed by the following TRIZ-methods and tools:

- Cause-effect-chain-analysis
- Function analysis
- Resources.

3.1. Cause-effect-chain-analysis

The test results with the special wiping device as described above showed the following disadvantages:

a) wire hits wiping device
b) coating blocks up wiping device
c) wire cannot find bushing
d) wire blocks up wiping device

To solve these problems the key problems were identified by the cause-effect-chain-analysis.

3.1.1. Cause Effect Chain 1

Wire hits wiping device

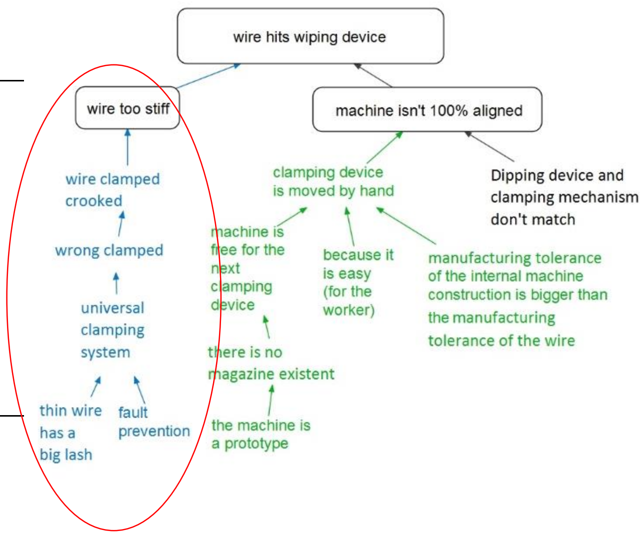

Fig. 5. Cause-effect-chain-analysis for „wire hits wiping device“

The company is using a universal clamping system for their clamping device, because its function is easy to be understood by unskilled employees without further training and the clamping device can be used for the production of several product variants. The discussion pointed to the fact that the clamping device had too much tolerance, which led to more or less tension and bending of the inserted wires. Consequently they are not always inserted vertically, but in different directions, and they do not always reach the desired spot for wiping, sometimes they even miss the perforation of the wiping device distinctly.

3.1.2. Cause-Effect Chain 2

Wire cannot find bushing or blocks up wiping device

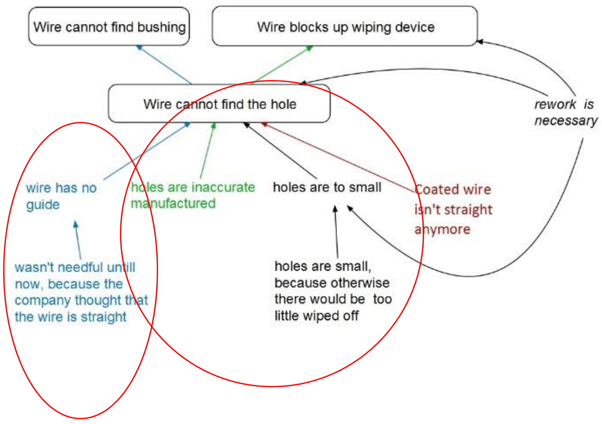

Fig. 6. Cause-effect-chain-analysis for "wire cannot find bushing" or "blocks up wiping device"

Two aspects are shown here:

a) The In-house-tool manufacture did not work exactly, as the perforations for the guide wires were not always exactly in the middle, so that even guide wires which had been inserted precisely, could not find their perforations.

b) The perforations were used as bushings. Therefore their diameter was the same as the diameter of the bushing used for manual coating. The wiping device should be closed around the guide wires for the dipping. But because of the small size of the perforations and the not straight insertion the guide wires missed the perforations of the wiping device and blocked it up. For using this wiping device it has to be opened, the wires have to be threaded manually into the perforations, and then the wiping device has to be closed again manually.

3.1.3. Cause Effect chain 3

Another reason, why the wires missed the perforations, could be the fact that the wires had no guidance in the bushing besides the clamping at the above end. This point was not considered here, because it was assumed that the uncoated wires are mounted vertically in the clamping device.

3.1.4. Cause Effect chain 4

Coating blocks up wiping device

A further disadvantage of the current solution was the fact that the wiped off coating solution sticks to the wiping device and eventually blocks the perforations, because the room temperature stimulated evaporation of the solvent as the machine was not a closed system with a lower temperature than the ambient temperature. Besides there was no alternative solvent with less vapour pressure. A higher room temperature also resulted in a faster drying process, and of course, the employees felt better with a pleasant room temperature.

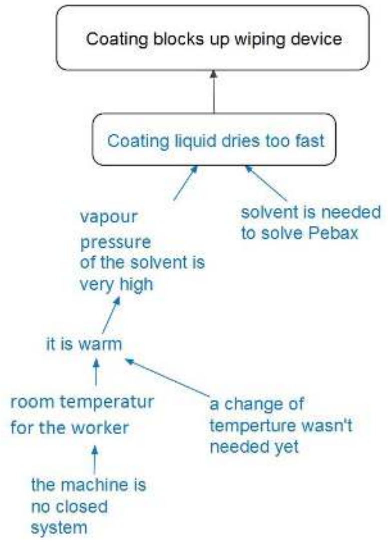

Fig. 7. Cause-effect-chain-analysis for "coating blocks up wiping device“

On the basis of the results of the cause-effect-chain-analysis first of all those key problems concerning the core of the coating process were searched: the wiping off of the excess coating solution.

To find new solutions for the analysed problems a closer look at the following aspects was taken:

- wire cannot find perforation – size of the perforation in the wiping device
- wiping device agglutinates – temperature of the coating solution.

3.2. Function analysis

For a more detailed problem analysis a function analysis was performed to locate the problems in the dipping device more precisely.

Main function of the dipping device: guide wire holds coating solution. The Target is the coating solution.

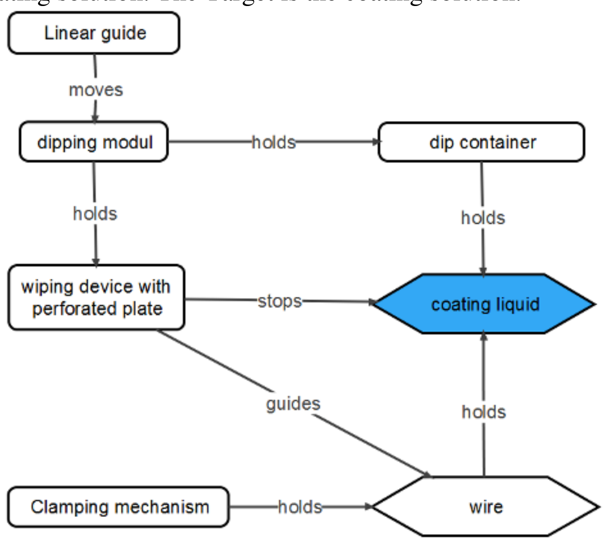

Fig. 8. Function Model of dipping device as "useful" system

After modelling the system in its useful state, the problems - also analysed in the cause-effect-chain-analysis - were modelled as function disadvantages:

c) wiping device stops/bends guide wire (harmful interaction)
d) wiping device guides wire insufficiently (insufficient interaction)
e) wiping device holds coating liquid (harmful interaction)
f) missing interaction between wiping device and guide wire (wire cannot find bushing).

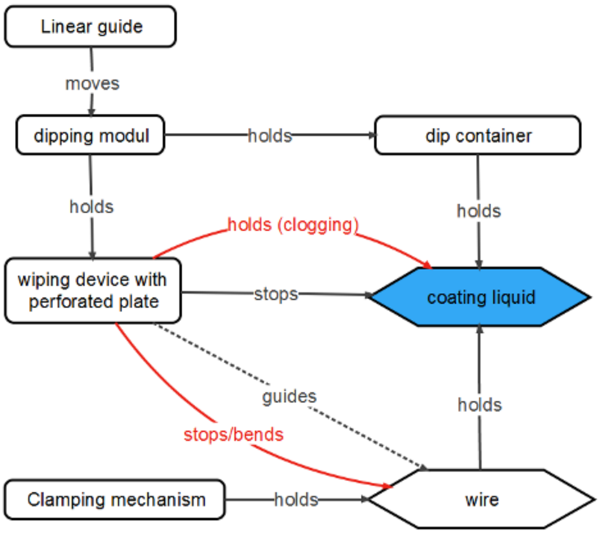

Fig. 9. Function Model of dipping device including function disadvantages

These are the questions deduced from the function analysis:

- How could be prevented the bending of the guide wire by the wiping device?
- How could the wiping device guide the guide wire more efficiently?
- How could be prevented the wiping device from holding the coating solution?
- How could be made sure that a useful interaction (e.g. guiding) is established between the wiping device and the guide wire?

The main points of the cause-effect-chain-analysis as well as the questions of the function analysis showed us the direction for formulating the problem models.

3.3. Available resources

To use the full potential for the search for solutions the available resources were collected.

The dipping device is located in a cleanroom and is therefore exposed to the same surrounding conditions all year. The following resources are available:

- compressed air
- power
- UV-light
- consistent ambient temperature
- air
- power
- Nitinol
- Pebax-solution
- linear guide
- wiping device with different perforation sizes
- humidity
- gravitation
- heating device of other devices in the room
- unused room
- employee

4. Finding of solution

During the problem analysis it was clear that the main problems were based on the design of the wiping device, the drying properties of the coating liquid and the possible imprecise clamping of the guide wires. With the results of the problem analysis the phase of idea generation and solution finding based on TRIZ problem models and solution principles were started.

In the next step, Engineering and Physical Contradictions from the current results of the problem analysis to aim at the wiping device were deduced.

4.1. Formulation of Engineering and Physical Contradictions concerning the wiping device

EC 1:	If a wiping device is used redundant material is wiped off, but the wires are prevented from dipping into the coating solution.
EC 1 inverted:	If no wiping device is used, wires dip into the coating solutions without problems, but redundant material is not removed.
EC 2:	If a wiper is used the wire tip will be fine, but the wiper will be agglutinated.
EC2 inverted	If no wiper is used the wiper will stay clean, but the tip gets wrinkles.

This boiled down to the following physical contradictions:

PC 1:	The system dipping device should have a wiping device to receive a fine tip. should not have a wiping device to prevent attaching.
PC 2:	The system wiping device should have wide perforations, so that the

wire can easily penetrate.
should have narrow perforations, so that the redundant coating liquid can easily be wiped.

4.2. Formulation of contradictions regarding the drying and sticking of the coating liquid

Engineering contradictions

EC 2: If the system is cooled,
the coating does not dry,
but the coating remains too damp at the wire.

EC 2 inverted: If the system is heated,
the coating on the wire dries well and fast,
but the coating liquid blocks up the wiping device.

Physical contradiction

PC 1: The system dipping device
should *be cool*, so that the coating stays liquid and the wiping device keeps clean
should *heat up*, so that the coating on the guide wires can dry well.

The noted contradictions were worked through by using separation principles and the 40 inventive principles. All single ideas were drawn or written down, together with sketches and concept drawings.

5. Solution Concepts

The evaluation of the single ideas lead to two solution concepts that were proposed and discussed with the tool manufacture for feasibility.

5.1. Concept A:

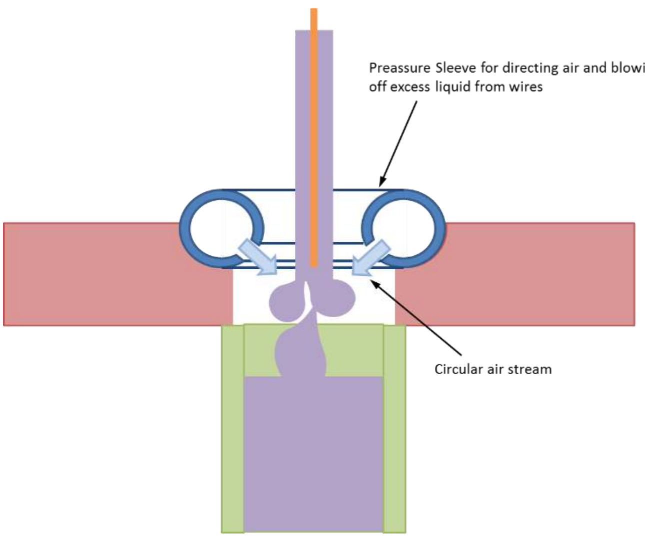

Fig. 4. Air sleeve concept

Pressurized air (available Resource) is used to blow off excess coating liquid after the wires have been dipped into the solution. The air stream should come from all sides to achieve an even coating thickness, thus a ring-shaped “pressure sleeve” that surrounds the guide wires and is positioned directly at the openings of the perforated board was proposed. These sleeves feature small openings through which the air is blown. Additionally, the air improves the drying process (forced convection) at the coated guide wire, so the overall temperature of the coating liquid in the container can be lower, preventing clogging and sticking of the liquid. Additionally, the stream of air could be designed as a spiral, cyclone-like stream for even coating and cooling of the solution at the guide wires.

5.2. Concept B:

A wiping device consisting of wedge shaped funnel-bushings is proposed with a 1mm opening at the bottom and a larger opening at the top (separation of big and small hole in space). The funnel-bushings are positioned in the holes of the perforated board and with their funnel-shape provide an effortless “self-guiding” of the wires, even if they are not mounted exactly straight in the clamping device. The small opening at the bottom executes the wiping-function.

Concerning the danger of drying coating liquid blocking the opening, a re-formulated function model of the problem zone revealed, that there should be no possibility for the solvent to evaporate in the area where the wiping happens.

Concerning the concept of ideality and using resources lead to a concept where the coating liquid itself stops the air from moving/”extracting” solvent from the coating liquid. Thus the lower part of the funnel-bushings were designed to be placed inside of the coating liquid, so no air is available in the area of the small wiping hole, preventing drying and conglutination in this zone.

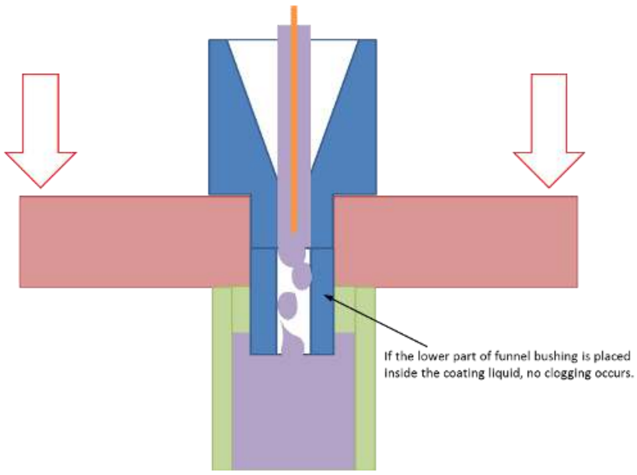

Fig. 4. Funnel bushing, final concept

5.3. Selection of solution concept

The solution concepts were discussed with the in-house manufacture regarding feasibility. Concept A was rejected as being too complicated and expensive for in-house manufacturing. Concept B was chosen, and 14 funnels were produced, so that each funnel - sitting in the perforated plate with seven perforations per side - takes in one guide wire. Featuring a wide opening on one side, the funnels make sure that there is enough space for imprecise hanging in the clamping device, whereas at the same time the funnel shape guides the wire evenly to find the narrow perforation at the bottom that takes care of wiping off the coating solution.

The funnels were initially tested in a manual test-run. The test showed very even and satisfying results. The testing of the funnels mounted inside the dipping device has still to be prepared by the tool manufacturer.

6. Current state of the project and future prospect

The resulting ideas and concepts are in a pilot project as indicated by the companies guideline mentioned at the beginning of this paper.

As a future development (depending on order volumes) a newly designed, automatic dipping device might be designed using the solution concepts provided through this work with TRIZ-tools.

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