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D2.2 Defined demonstrator device incl. personalised requirements

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Executive Summary

This document specifies the demonstrator device of the Openmind project. The specifications show the ranges of possible individualisation by the customer. The specification indicates tolerances for these customisable characteristics. It also lists other parameters of the demonstrator device, that will not be accessible by the customer but that will be used to balance the process and the properties of the device depending on the choice of customisable parameters. Technical drawings illustrate the specification of the devices.

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1 Introduction

This deliverable is a result of Task 2.2 Definition of demonstrator devices. This task aims to identify and specify demonstrator devices that will be produced and monitored by their personalised requirements at the end of the Openmind project.

Appropriate demonstrators are necessary to verify and validate the results of the whole project. Along with the demonstrator a clear definition of the ranges of individualisation is given. The variables of the demonstrator device will be diameter, length, stiffness, marker material, count and position, coating material.

The demonstrator device may be a basis for further developments of this or other types of devices.

The work for this deliverable has been carried out by Fraunhofer IPT as leading party, primarily supported by Nano4Imaging. The other hardware developing partners Blueacre, Gimac, TCD also contributed significantly to the deliverable.

2 Preliminary work

2.1 Selection of device type

The Openmind project is positioned in the field of medical device manufacturing, more precisely it is aiming at the development of minimally invasive medical devices. The future Openmind process chain will be able to manufacture elongated devices with a high aspect ratio. Regarding this geometrical restriction different kinds of devices exist in the specified field of activity. In detail these are:

- solid devices with a full cross section like guide wires
- hollow devices with a ring shaped cross section like catheters or needles
- complex devices, assembled from various components like functional catheters or micro-instruments

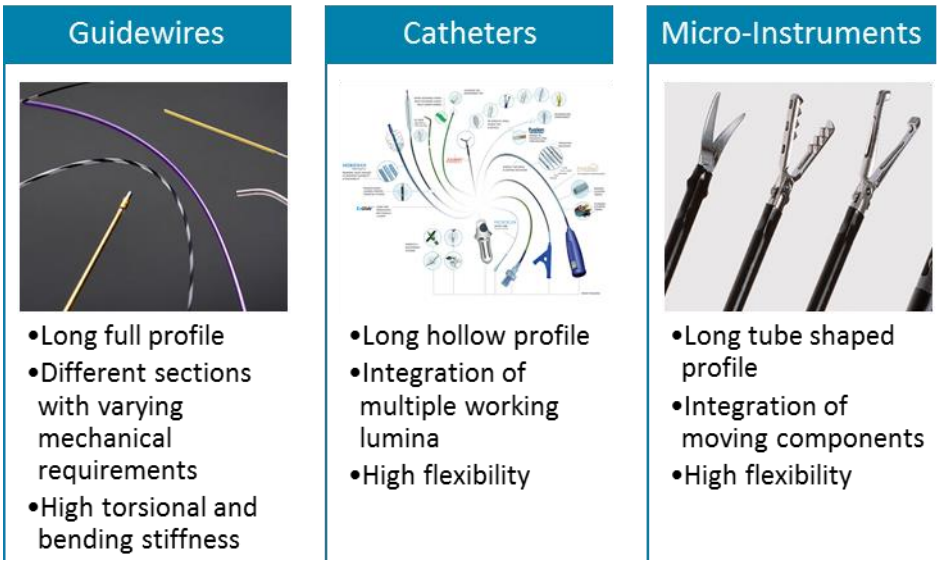


Figure 1: Different types of minimally invasive devices with high aspect ratio

Figure 1 shows characteristic properties of these types of devices. The Openmind project focuses on reducing handling procedures to a minimum. Devices, that require extensive handling or assembly procedures by their design, should be left out for using it as a demonstrator. Therefore, the category of functional catheters and micro-instruments has been ruled out for use as demonstrator device.

The Openmind process chain is designed to be used for the manufacturing of individualised disposables. One key aspect of the Openmind process chain is the individualisation of the mechanical properties, which will be realised by the FRP components in the process chain. Different mechanical properties along the longitudinal axis of the device are a characteristic of guide wires. Therefore, the category of guide wires is focused in the project.

2.2 Market overview

The following table shows characteristic properties of commercial state-of-the-art guide wires from different medical device manufacturers. The overview shows the variability of these devices, that is currently available on the market.

Table 1: Properties of commercially available guide wires

Manufacturer	Type	Diameter	Length	Flex. Length	Coating
Terumo	Radifocus Guidewire M Stiff type (stiff / half stiff)	0,020“, 0,025“, 0,035“, 0,038“	80, 150, 180, 260, 300 cm	10 mm, 30 mm, 80 mm	Polyurethane layer containing tungsten "M" polymer (hydrophilic)
Terumo	Radifocus Guidewire M Standard type	0,018“, 0,025“, 0,032“, 0,035“, 0,038“	50, 80, 120, 150, 180, 220, 260 cm	10 mm, 30 mm, 50 mm, 80 mm	Polyurethane layer containing tungsten "M" polymer (hydrophilic)
endox Feinwerktechnik	Führungsdraht PU extrudiert Führungsdraht PTFE	0,035“ (± 0,03 mm)	50, 60, 65, 70, 75, 80, 100, 125, 150, 180, 300, 400, 460 cm (± 5 mm)	50 mm	Polyurethan PTFE Hydrophilic
Nano4Imaging	MR-Wire	0,035“	200 cm	30 mm	Pebax
EpFlex	MR-line	0,032“, 0,035“	up to 480 cm	up to 300 mm	Pebax Hydrophilic
Boston Scientific	Starter Guidewire	0,025“, 0,035“, 0,038“	80 cm, 150 cm, 260 cm	30 mm, 40 mm	

Manufacturer	Type	Diameter	Length	Flex. Length	Coating
Boston Scientific	Amplatz Super Stiff	0,035“ 0,038“	145 cm	35 mm 60 mm 70 mm	PTFE
Merit Medical	InQwire Diagnostic Guide Wire (also super stiff)	0,018“, 0,021“, 0,025“, 0,032“, 0,035“, 0,038“	50, 70, 80, 100, 125, 145, 150, 180, 200, 210, 260 cm	N/A	Heparin
Merit Medical	Merit H_20 Hydrophilic Guide Wire (standard/stiff)	0,018“, 0,025“, 0,035“, 0,038“	80, 150, 180, 260 cm	N/A	

The Openmind demonstrator device shall cover a broad spectrum of the existing devices in the field of minimally invasive guide wires. Therefore, the market overview is screened for characteristic properties or ranges of values.

- Some manufacturers offer their products in several variations with differing stiffness. The amount of stiffness is not quantified but is indicated qualitatively (“standard”, “stiff”, “super stiff”, “half stiff”)
- The diameter of the listed devices differs from 0,018’’ to 0,038’’. The larger sizes are more frequent than the smaller ones. The most common size is 0,035’’ (available from every manufacturer), followed by 0,038’’. From the smaller range, the devices with diameter 0,025’’ and 0,018’’ are more available.
- The full length of the device is available in very broad variation starting from 50 cm up to 480 cm.
- The length of the most flexible part (“tip”) is varying in a range from 10 mm to 300 mm, with lengths between 30 mm and 60 mm being the most popular ones.
- The devices are available with different coatings (PUR, PTFE, Pebax, Hydrophilic, Heparin)

3 Definition of demonstrator device

3.1 Basic definitions

3.1.1 Type of device

The Openmind demonstrator device is of the type "guidewire". The guidewire is characterized by a full cross section.

3.1.2 Sections of the guidewire

The guidewire has at least two sections with different mechanical properties. The "tip" section is comparably short and has lower mechanical stiffness than the "shaft" section which extends over most of the length of the guidewire. Within the sections the mechanical properties remain unchanged.

3.1.3 Orientation of the guidewire

In medical terms, the two ends of the guidewire are named the "distal" and the "proximal" end. The tip of the guidewire is located at the distal end. The guidewire is introduced into the body (usually via a vessel) with its distal end. The guidewire is pushed until the distal end reaches the final position. At this moment, the proximal end is still located outside the body, as it is used for the manipulation (push, pull, torque) of the guidewire. The shaft section of the guidewire extends from the proximal end to the beginning of the tip section.

3.1.4 Composition of the guidewire

The Openmind guidewire is composed of a multi-layer structure:

Core layer:	FRP profile with reinforcing fibres oriented along the longitudinal axis of the profile, providing bending stiffness
Inner winding layer:	fibres wrapped around the core layer with variable orientation, providing additional bending stiffness and torsional stiffness
Outer winding layer:	fibre wrapped around the inner winding layer with variable orientation (usually opposite to direction of inner winding layer), providing additional bending stiffness and torsional stiffness
(Visibility) markers:	ring-shaped elements printed on the surface of the outer winding layer, providing visibility of the guidewire in different medical imaging modalities
(Extrusion) Coating:	outmost layer of the structure, covering the outer winding layer and the markers, generating the outer diameter of the device, eventually contributing to stiffness and visibility

3.1.5 Substructures

The following substructures are named for the purpose of unambiguity:

Profile:	assembly of the FRP components core layer, inner winding layer, outer winding layer
Mandrel:	assembly of profile and visibility markers, used as input for the coating process
Device:	final assembly of the extrusion coated profile, covering all layers of the structure

3.2 Identification of dimensions of individualisation

The options for individualisation are the main aspect of the definition of the demonstrator device. The basic set of dimensions derives from the following Figure 2:

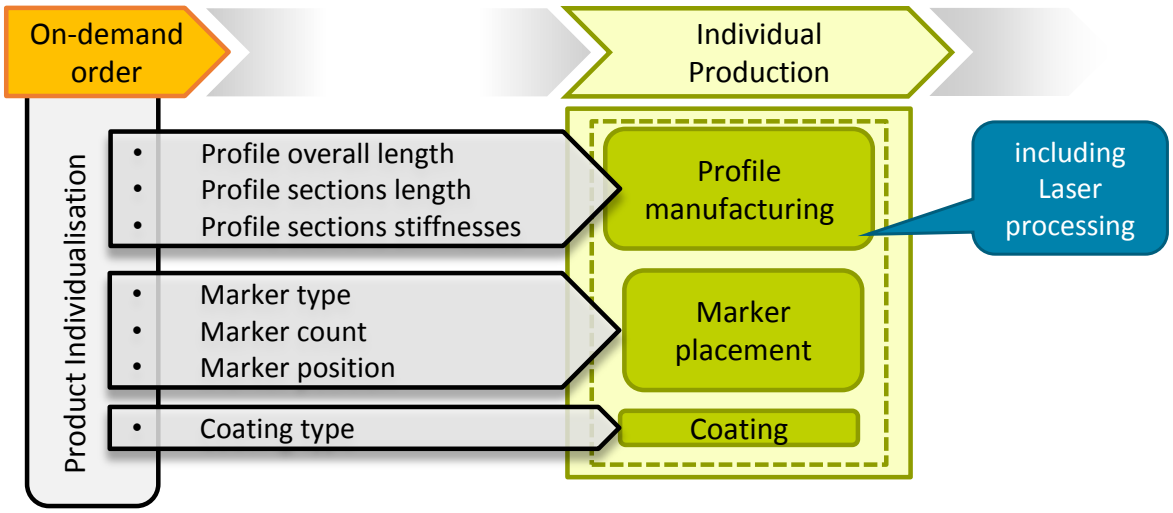


Figure 2: Initial set of dimensions of individualisation

This initial set is divided according to the different stations in the Openmind process. The set represents the parameters, which will be open to be defined by the customer. In Table 2, these parameters are grouped under the types “custom (card.)” or “custom (nom.). The type “custom (card.)” contains parameters that can be individualised on a cardinal scale (the parameter can be specified by a number, which can be chosen freely from a given range of values). The type “custom (nom.)” is characterised by a nominal scale. These parameters are selectable from a given set of non-numerical values.

The initial set of dimensions is expanded by parameters that are fixed for a certain machine setup and thus cannot be changed in the running process. These parameters will only be changed by stopping the process, installing a new setup and restarting the process. These parameters are marked as “static”.

The third category of dimensions is from type “internal”. These parameters can be varied within a characteristic range but will not be open for individualisation by the customer. The variation of these parameters either will be used to balance the process or is determined by other (customised) parameters.

Table 2: Dimensions of individualisation

Dimension	Contributor	Type	Explanation
Overall diameter	all	static (nom.)	Outer diameter of the device
Profile composition	IPT	internal	type of roving and resin
Profile diameter (core, winding)	IPT	internal	restricted by forming die size and roving count

Dimension	Contributor	Type	Explanation
Profile length	IPT	custom (card.)	
Section length	IPT	custom (card.)	
Section stiffness	IPT	custom (nom.)	depends on composition, diameters (core, winding), winding angle, coating
Profile diameter (core, winding)	Blueacre	internal	change of diameter after curing in forming die; used to balance changes in winding angle
Surface structure	Blueacre	internal	local structure for marker printing or coating
Marker type	TCD	custom (nom.)	restricted by number of available inks in setup
Marker count	TCD	custom (card.)	
Marker position	TCD	custom (card.)	
Marker width	TCD	internal	restricted by size of the cliché; determined by desired contrast of marker
Marker thickness	TCD	internal	restricted by viscosity of ink and depth of cliché
Coating type	Gimac	custom (card.)	restricted by number of available coatings in setup; influence on stiffness and/or visibility
Coating thickness	Gimac	internal	realizes outer diameter of the device
Section length	Gimac	internal	derives from mechanical and visual properties

3.3 Definition of custom dimensions

This section defines the custom dimensions of the device regarding their ranges (min. value, max. value) and tolerances (if applicable).

3.3.1 Profile length

The Openmind process will be a continuously running process being able to produce

devices with very long length. However, for the individualisation by the customer, the length will be limited to a specified range.

	min. value	max. value	Tolerance	Comments
Profile length	500 mm	4.800 mm	± 2 mm	

3.3.2 Section length

A section is defined by an area of unchanged mechanical properties. Between two sections with different mechanical properties a transition with a specified length has to be made to allow the process to adapt the properties smoothly. This smooth transition will prevent kinking of the device.

	min. value	max. value	Tolerance	Comments
Section length	10 mm	[Profile length]	< 20 mm	tolerance due to transition

3.3.3 Section stiffness

The stiffness of the sections is usually not quantified by the manufacturer, but indicated in a qualitative manner (soft, standard, stiff, super stiff).

	min. value	max. value	Tolerance	Comments
Section stiffness	250 N/mm²	10.000 N/mm²	± 10%	

3.3.4 Marker type

The marker will be used to generate visibility in different medical imaging modalities. Different imaging modalities require different types of marker material.

	Type 1	Type 2	Type 3	Comments
Marker type	MRI low concentration	MRI high concentration	Fluoroscopic contrast	

3.3.5 Marker count

The number of markers is one of the key dimensions for customisation, because it affects the visibility of the device significantly. At least one marker at the tip of the device is obligatory.

	min. value	max. value	Tolerance	Comments
Marker count	1	dependent on length	N/A	

3.3.6 Marker position (distance)

The marker position is restricted by the smallest possible distance between two prints.

	min. value	max. value	Tolerance	Comments
Marker position	2 mm	[profile length]	±1 mm	

3.3.7 Coating type

The type of coating may affect the mechanical properties as well as the visibility properties or the friction of the device.

	Type 1	Type 2	Type 3	Comments
Coating type	hard touch (shore hardness)	soft touch (shore hardness)	radiopaque	only 2 types per setup

3.4 Definition of static dimensions

This section defines dimensions, which cannot be varied in a running process due to technological limitations. However, these dimensions may be opened to customisation. In this case the machine setup has to be changed for different production runs.

3.4.1 Overall diameter

The overall diameter specifies the size of the final device. In the project two common sizes shall be available.

	Type 1	Type 2	Tolerance	Comments
Overall diameter	0.018'' (0,45 mm)	0.035 '' (0,89 mm)	±25 µm	

3.5 Definition of internal dimensions

The internal dimensions are used to balance different choices of the customer. These dimensions are related to internal parameters of the process models. The exact ranges of values and tolerances will be specified during the preliminary tests of WPs 4, 5 and 6.

From further investigations, the following values and tolerances can be assumed.

Table 3: Internal dimensions

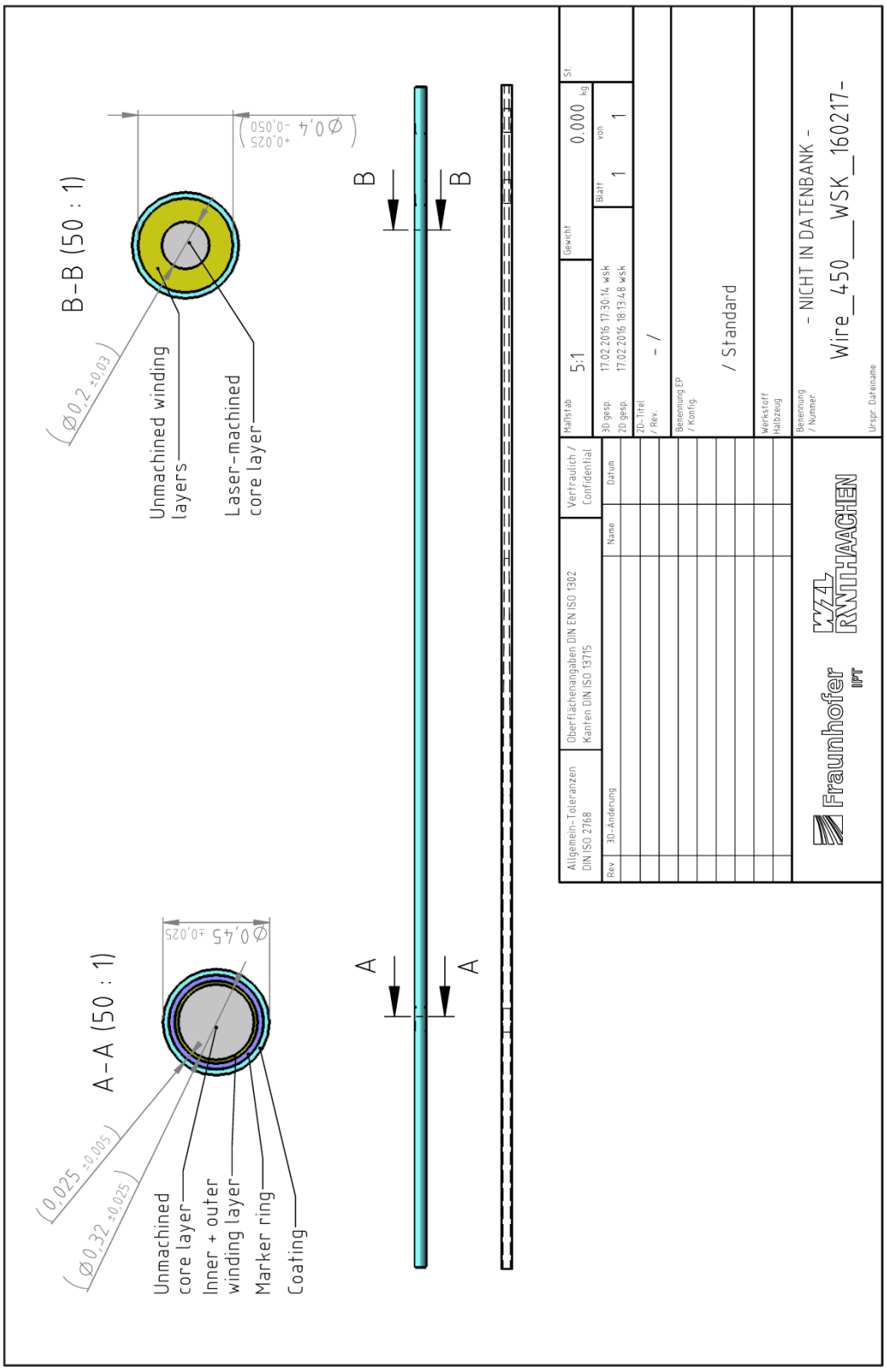
	min. value	max. value	Tolerance	Comments
Profile core diameter	0,2 mm	0,8 mm	±25 µm	
Profile winding diameter	0,4 mm	1,1 mm	+25 µm -50 µm	
Marker width	0,5 mm	2 mm	±0,1 mm	
Marker thickness	15 µm	50 µm	±5 µm	depending on concentration
Coating thickness	0,01 mm	1 mm	±5 µm	

3.6 Technical drawings

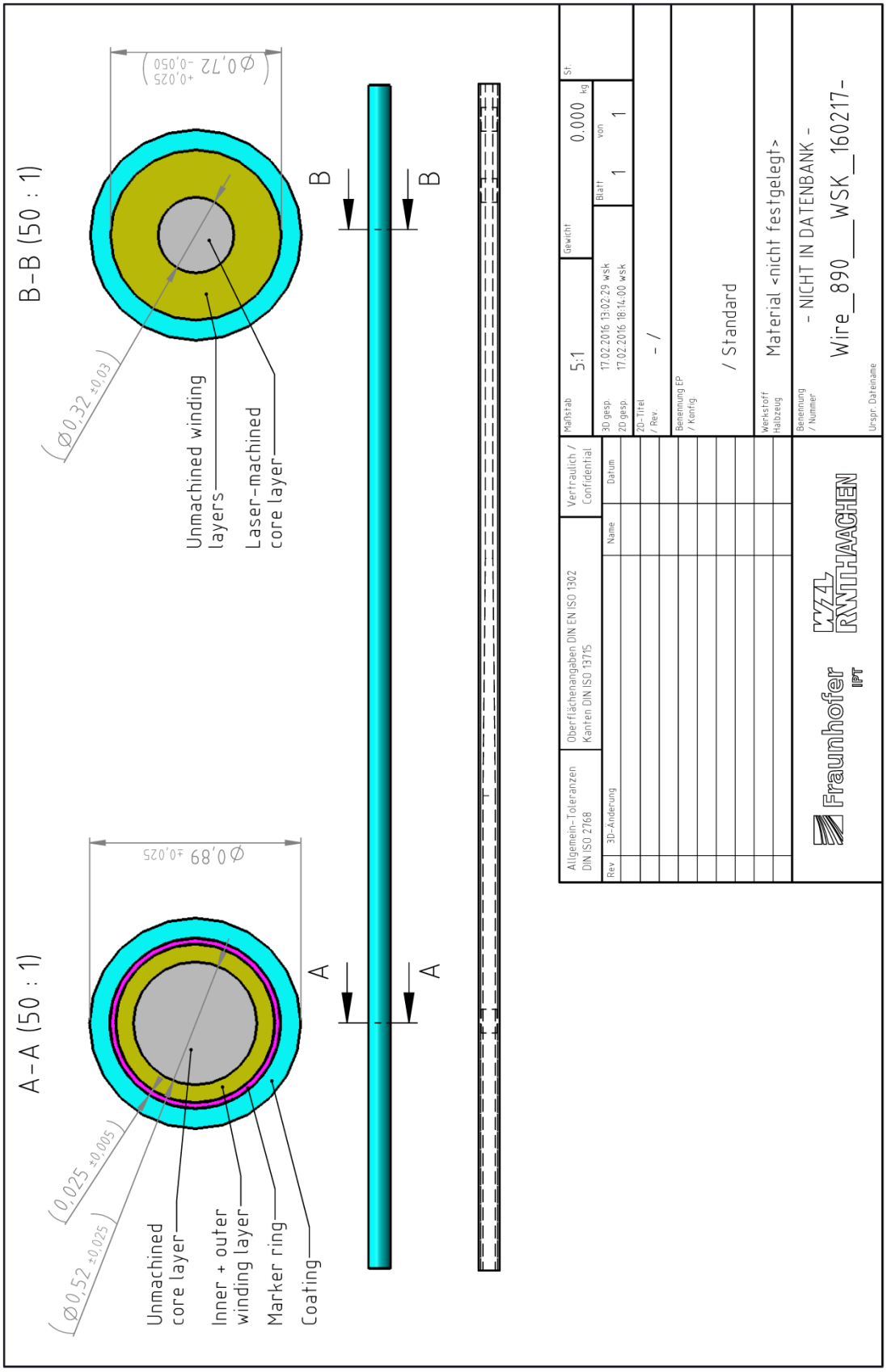
The following sections contain technical drawings of the two chosen demonstrator devices. For compatibility reasons, the outer diameter is fixed. As the individualisation of the device is the key aspect of the project, all other (bracketed) dimensions represent a first estimation of commonly configured values.

Each drawing is composed of a coloured side view of the profile with two characteristic cross sections. The cross section A is located in the stiff part of the profile, whereas the cross section B represents a soft part. A transparent version of the side view shows the composition of the profile (varying layer thickness) and possible positions of the marker rings.

3.6.1 Demonstrator device Type 1 (0.018'')



3.6.2 Demonstrator device Type 2 (0.035'')



4 Conclusions

The demonstrator device was specified based on the information from a market review. Two common sizes were chosen for the static parameter “overall diameter”. The dimensions of individualisation were specified independently from the size.

The specification of dimensions of individualisation for the demonstrator as well as additional internal dimensions include the expected achievable tolerances. These information will feed into the activities for the enhancement of the existing process technologies in WP 4/5/6.

The results will also be used for the definition of the design of experiment in D2.3