Microsystem Technologies

Piezoresistif microsensors for an instrumented medical needle for its real time monitoring in a microlocalization tool

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Piezoresistif microsensors for an instrumented medical needle for its real time monitoring in a microlocalization tool

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Keywords: microgauges; piezoresistivity; microfabrications; medical needle; microlocalization, monitoring.

I - Introduction

In the field of interventional radiology, when a physician wants to make a puncture or a biopsy for example, he must insert a long medical needle in the human body. This instrument can be deformed by its environment and miss its target.

To facilitate the guidance of medical devices in the human tissues, localization and navigation tools have been developed to view, in real time and in a virtual environment representative of the reality, the target, the pattern position of the instrument and its projected path. The assistance provided to the physician by these new tools able to guide the instrument to more accurately target with decreased morbidity.

However, current localization and navigation tools make the assumption of the non-deformability of the instrument used, often unchecked assumption in current practice. Indeed, the interactions of the deformable instrument with human tissues (soft tissues, bones, hard obstacles, or others) is causing deformations of the instrument that may result in the failure of interventional medical procedure.

II – Current practices in interventional radiology

In the practice of surgery, various imaging means are used to detect the deformation of the medical device inserted into the human body. The most frequently used methods are ultrasound, Magnetic Resonance Imaging (MRI) and fluoroscopy [1-3].

The advantage of ultrasound is that it is a technique virtually harmless and painless for the patient. Moreover, this is one of the only real-time imaging techniques, with which one can always trace the synchronous movement of medical tools and query in real time the state of organs. The main disadvantages include first the lack of sharpness of the image, due to the depth limit that the ultrasonic waves can reach. Moreover, measurements and image quality depend greatly on the position of the probe, and thus, the ability and skill of the practitioner.

MRI imaging is more effective for determining the position of the target of the surgery, relative to the position of the instrument. A constraint on the application of MRI is related to the compatibility issue that may result in unexpected movement of the medical tool containing ferromagnetic materials. The use of MRI for the detection of the medical device must be very careful to avoid any parasitic effect on other devices.

Fluoroscopy is a form of diagnostic radiology performed with special equipment that allows the radiologist to view on a TV monitor, the body with the help of contrast medium. The introduction of X-ray as a radiation source brings potential risks to patient health and also to the medical staff. In terms of imaging quality, the existence of parasitic effects such as Lubberts effect, makes the displayed less sharp image, especially for mobile objects.

In conclusion, these imaging methods give clinicians a clear and direct perception of the deformation of the medical instrument in the human body. However, application of these methods is hampered by some existing defects in the accuracy and compatibility, including:

• For ultrasound and similar methods, the image clarity is compromised by the inability of the ultrasound to reach the depth in the human body.

• The magnetic field disturbance produced by the movement of the medical instrument can also damage the clarity of the image on the screen.

• Most imaging display the 2D shape of the instrument, which does not reflect the reality of its deformation. An analytical model for reconstructing the 3D deformation is not always available.

• Irradiation with X-ray would be a potential risk to patient health and to the medical staff.

• The image-formation period may be too long for the simultaneous visualization of the needle and the target, based on which the clinician can adjust in real time the surgery.

Faced with these difficulties, it appears necessary to enrich the virtual environments of navigation and representative of reality, giving them the ability to track the exact position of all the deformable instrument and distorted in order to specify, in real time, the relative positions of the instrument, its extremity and the target.

So in our work, we propose to instrument a needle with microgauges. These microsensors allow to measure in real time, during its use, the strain of the needle. We can calculate from this strain the real shape of the needle and give it to the physician, in a previous medical image of the patient.

III - PREVIOUS WORKS

In this project, various activities were already carried out.

First we have used Finite Element Modelization (FEM) to determine the operation of an instrumented needle. The mechanical analysis of the needle is based on beam theory. FEM is also an alternative to calculate the variation of the deformation at specific locations, depending on the displacement of its end. So we also use it to size the microsensors. In parallele, we did an analytical study. The results of the calculations from the theoretical analysis and the FEM simulation were perfectly coherent.

After, the proof of feasibility has been made, with a macro-instrumented prototype of a needle, with commercially microjauges glued on its surface. This prototype has been experimented and has shown the feasibility and the characteristics of such a device [4].

Next, a first microfabrication of microsensors, directly on the body of the needle, has been carried out in a clean room. We have chosen microjauges operating on the principle of the piezoresistivity. This means that during the deformation of the needle, the microjauge on the surface will be deformed, that will cause the change of the value of its resistance [5]. The microgauge is connected to an instrumentation electronic card which measures the variation of the voltage, allowing the calculation of the variation of the resistance of the microsensor. It allows also the calculation of the deformation and of the deformed shape of the needle. The actif material of the microgauges is the germanium.

Classically, the used substrates in clean room are silicon or glass wafer. So we must adapt the process to the unconventionnal geometry and material of the substrate (needle is circular and in stainless steel). For that, we have designed a special support in which we can insert the needles [5]. But this support is particularly heavy, so the different parameters of the microfabrication must be adapted (for the spin coating and photolithography for example).

The results of the first microfabrication show that we are able to instrument a needle by microfabrtication. The microgauge has a U shape with two gold bonding pads for the experimentation. It is 500 µm long, 150 µm width and 400 nm thick [5].

The experimentations of this first micro-instrumented prototype have shown that the microgauge works very well [5], but that the gauge factor (GF) was not as high as that expected (3 versus 45 while commercially gauges have a GF of 2).

So different ways must be explored to improve the process.

IV – NEW MICROFABRICATION

At first, we have shown that it is because the cristallization annealing do not cristallize correctly the Germanium, that the gauge factor was not as high as expected. The informations taken in a paper [6] does not seem perfectly reproducible on our application. So we have explored the way to improve the cristallization. There are three crucial parameters in the cristallization annealing: the duration of the annealing, the temperature of the annealing and the thickness of the metal for the MIC (Metal Induce Cristallization). Samples were made and measures were done with XRD (X-Ray Diffraction) to find the good parameters which allow a better cristallization of the germanium. The results of the XRD measures show that the thickness of the gold layer is too thin (20 nm), it must be 40 nm thick to have a good cristalization with an annealing of two hours at 300°C.

New parameters of the process was therefore established. A new support were design, thiner than the previous (2 mm instead 5). Photolithography masks were designed for the new micro-instrumented prototype. The microfabrication process remains the same (fig. 1).

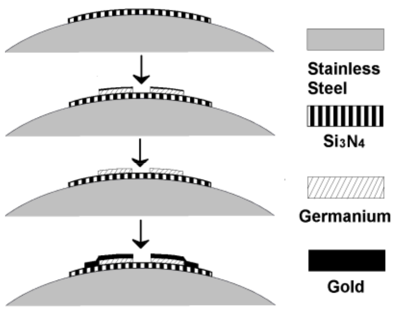


Figure 1: process of the microfabrication of the new prototype

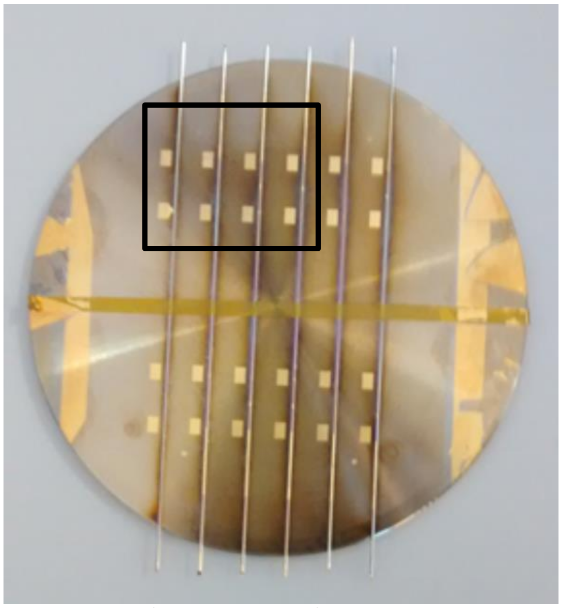


Figure 2: Photo of the new support after the silicon nitride and the germanium/gold layer after lift-off

At first, a layer of 200 nm of silicon nitride is deposited by sputtering. The first photolithography allows to pattern the shape of the microsensor (U shape with the dimentions given previously in this paper). A germanium layer of 400 nm is deposited as piezoresistive material (actif material) of the microsensor, and a gold layer of 40 nm is deposited as Metal Induce Cristallization (MIC) material, the both by evaporation by lift-off. After, the annealing is done at 300°C during two hours. The second photolithography allows to pattern the connecting pads of the microgauges. A chromium/gold layer (10 nm/200nm) is deposited by evaporation by lift-off.

On this new micro-instrumented prototype, we made four microsensors on each needle, with six needles in the new support (fig. 2 and 3).

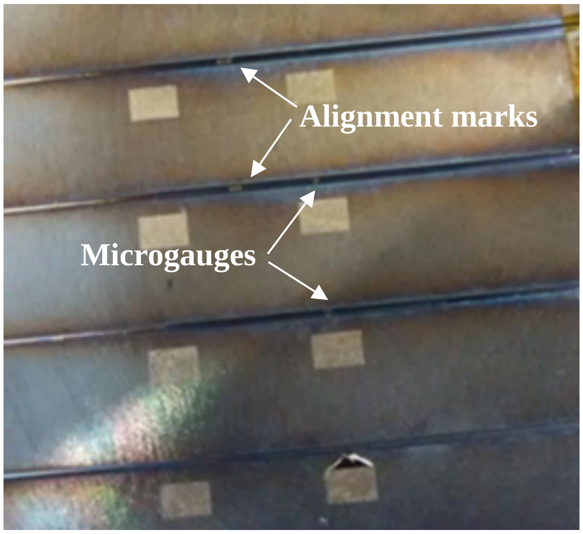


Figure 3: Zoom of the square on figure 2

The needle used for this fabrication are 10 centimeters long and have a diameter of 0.6 millimeters. It is in stainless steel.

We obtain microgauges to experiment (fig. 4).

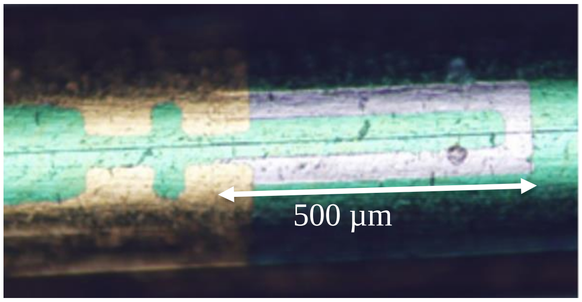
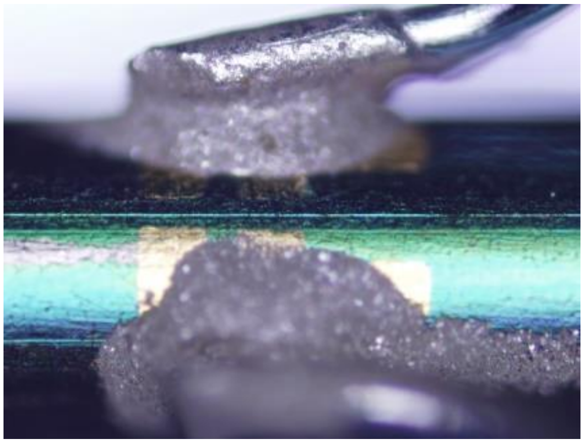
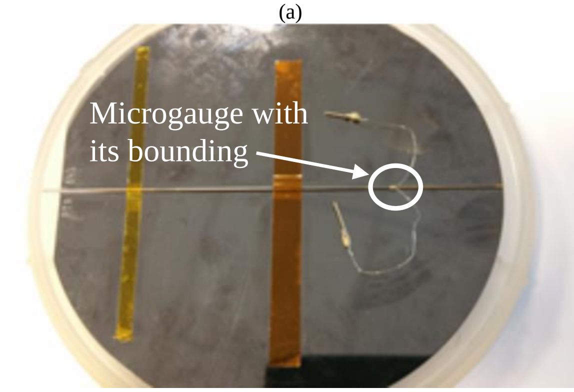


Figure 4: Photo of a microgauge with its bonding pads

The bonding was done on the connecting pads (fig. 5 (a)), on each microsensor that must be experimented.



(a)



(b)

Figure 5: Photo of the bonding of a microgauge (a), and of a needle with the bonding on one microgauge (b)

V – EXPERIMENTATIONS AND RESULTS

The test bench was renovated. We purchased new servomotors to mobilize the micrometric table (Thorlabs), and new bridge deformation measurement module (National Instruments) to be able to measure simultaneously the deformations of four microgauges.

The needle is fixed in a bracket (fig. 6), and the new test bench is presented on figure 7.

The experimentations were conducted like for the first prototype [5]. Because all the microgauges are on the same generatrix of the needle, we only displace the tip of the needle on one direction (x for example). We have shown previously that the transverse component is negligible in regard with the longitudinal one. So when the experimentation is running, LabVIEW register, for each measured point, the x position of the tip of the needle and the voltage across the microgauge.

Therefore, with the following equation (1), we can deduce the variation of the resistance.

$$V_{acq} = \frac{\Delta R_g}{R_g}.\frac{V_e}{4} \qquad (1)$$

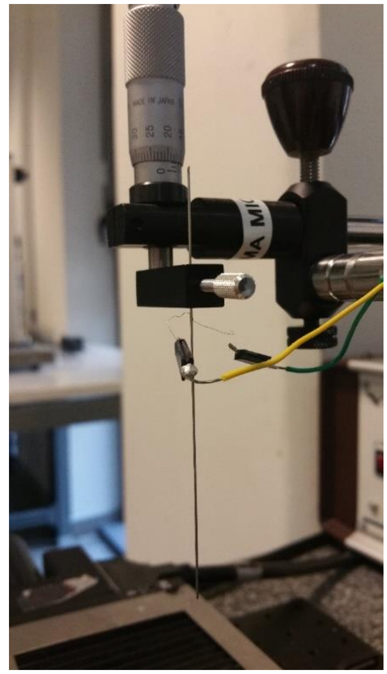


Figure 6: The needle fixed in the bracket

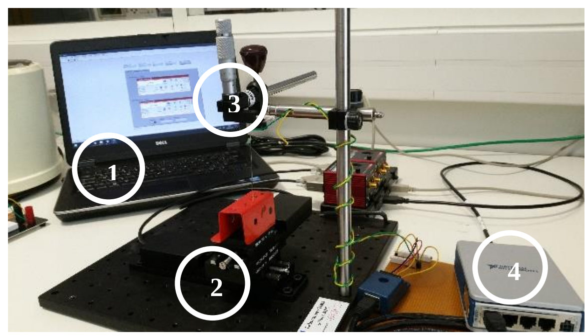


Figure 7: Test bench for the experimentations of the second micro-instrumented prototype: 1 is the PC with LabVIEW, 2 is the micrometric table, 3 is the bracket with the needle and 4 is the measurement module

Where V_{acq} is the measured voltage across the microgauge, R_g is the gauge resistance and V_e is the powered voltage.

$$\varepsilon = \frac{-3.D.(L_a - z)}{2.L_a^3}.\delta_x \qquad (2)$$

Where ε is the local strain, D is the diameter of the needle, L_a is the length of the needle between the clamping and the contact at the tip of the needle, (L_a-z) is the distance between the microgauge and the contact at the tip of the needle, and δ_x is the displacement of the tip of the needle.

The figure 8 shows the results of an experimentation of a microgauge, when the tip of the needle was displaced with a trajectory of 8 millimeters (4mm on each side from the non-deformed position of the needle). Therefore, figure 8 is the graph of the voltage ratio versus the displacement of the tip of the needle for eight same trajectories. This figure shows that we have a very good repeatability in the measures.

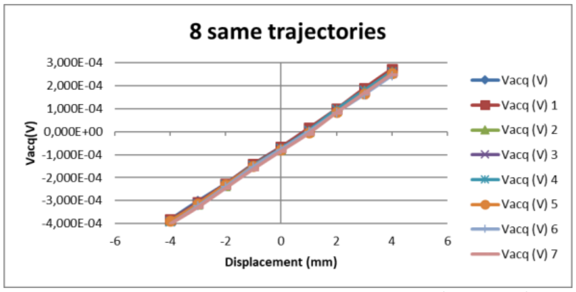


Figure 8: voltage ratio versus the displacement of the tip of the needle

With these results, we can determine the practical Gauge Factor (GF) to verify that we have improved it in the new microfabrication.

The GF is define by equation (3):

$$GF = \frac{\Delta R_g}{R_g.\varepsilon} \quad (3)$$

Where GF is the gauge factor, R_g is the gauge resistance and ε is the local deformation.

From equation 2 and 3, we can deduce [4]:

$$\frac{V_{acq}}{V_e} = -\frac{3.D.(L_a - z)}{2.L_a^3}.GF.\delta_x \quad (4)$$

n° exp	D	La	La-z	R	GF_{exp}	GF_{th}
1	0.6	77.6	71	2	19.07	45
2	0.6	73.6	70.8	2	20.49	45

Table 1: results for the extreme values of the GF

The different experimentations give an experimental GF between 19.1 and 20.5 (Table 1). The first prototype give us a theoretical GF of 45 and an experimental one of 3.12 (the average value). Therefore, with this new microfabrication, we have multiplied the GF by more than 6, which is a satisfactory result.

VI – Design and fabrication of the connecting tracks

After these good results, we must study the connection of the microgauges. For that, we design needles with their connecting tracks and bonding pads, to export the connections at the proximal extremity of the needle as shown on fig. 9 to 11.

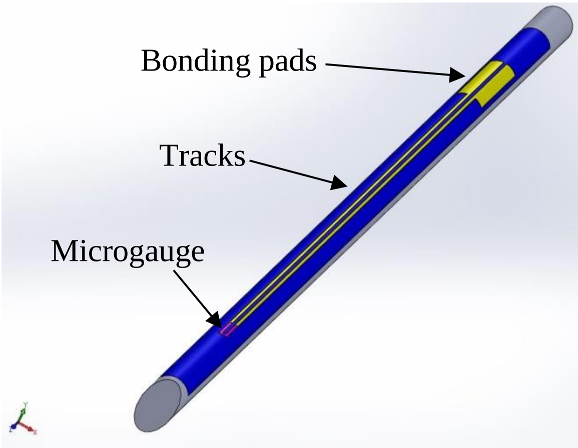


Figure 9: One microgauge with its connecting tracks and pads

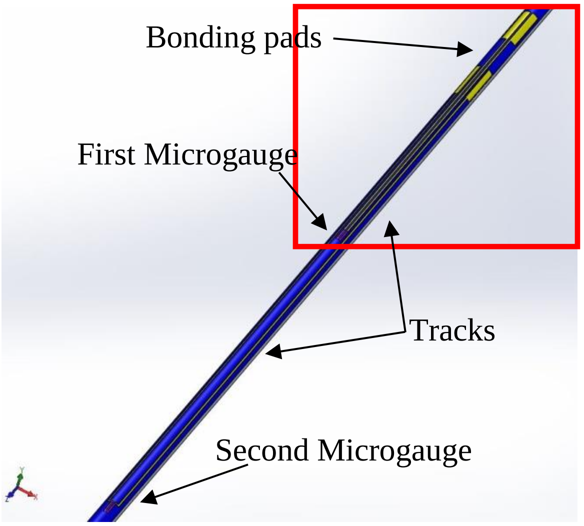


Figure 10: Two microgauges with their connecting tracks and pads on the same generatrix of the needle


Figure 11: Zoom of the square of figure 2

A microfabrication has been successfully made to obtain the new micro-instrumented prototype which are presented on fig. 12 and 13.

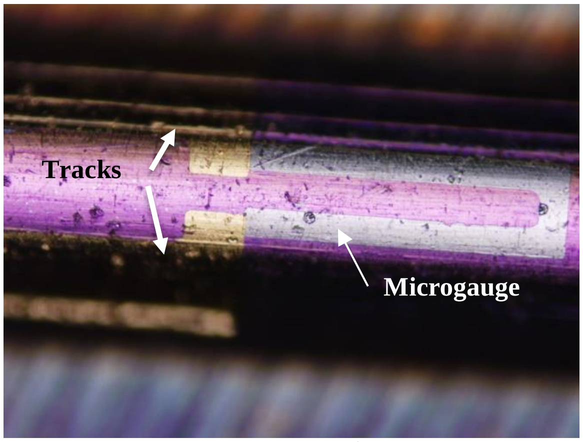


Figure 12: Microgauge with a part of its connecting tracks

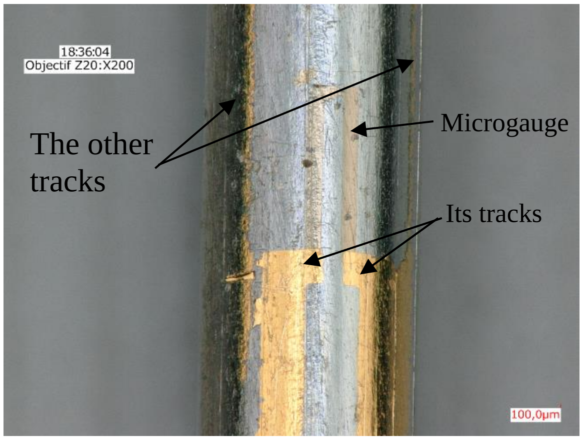


Figure 13: Another microgauge with a part of its connecting tracks, and with a part of the other connecting tracks of second microgauge like on figure 11

These microgauges can although been experimented with a bonding at the end of the connecting tracks.

VI - Design of the microconnector

To connect the needle with a microlocalization system, we must design a microconnector, because no solution exist commercially. So we have designed some solutions with simples principles like: diaphragm, slide, chuck, clothespin. Each solution have advantages and disadvantages. The most adequate is shown on figure 14. There is a fixed part and a mobile part, which “open” around an axe. On the figure 15, we shown the detail of the gripping part with a needle with tracks on three generatrix, which is our objective in a short term. This solution allow the relatively easy positioning of the needle. Connections are done by 100 µm wire integrated in the parts of the microconnector.

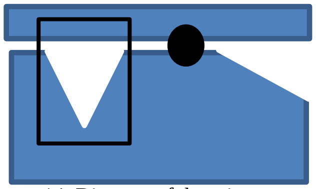


Figure 14: Diagram of the microconnector

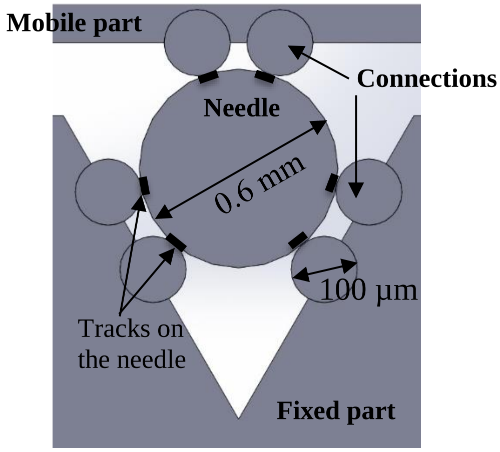


Figure 15: Detail of the square of figure 14

This microconnector is being manufactured.

VII - Conclusion and perspectives

Our works cover the complete study of the instrumented medical needle. It began with the modeling of the needle and the microsensors, and a proof of concept on a macro model. After we have developed the microfabrication process of the microgauges on the needle, and the experimentations of the first prototype show a poor gauge factor. So we have explored the reasons and made samples to test them with XRD. We have found better parameters for the annealing. We have then fabricate a second prototype and we have experimented it. The results was satisfactory, so we have focused on the connections of the microgauges at the proximal extremity of the needle. We have then made needles with microjauges and their connecting tracks, and obtained the expected result. Finally, we have design a microconnector to be able to connect the needle with three microsensors.

We have now to fabricate microgauges on three generatrix of the needle (figure 16). For this, we must repeat the same process three times, performing a rotation of the needle of 120° in its support between each process. The microconnector will allow us to connect the micro-gauges with the experimental test bench. We could then monitor the needle in three dimensions. In a longer term, we must integrate the prototype in a microlocalization system to test it.

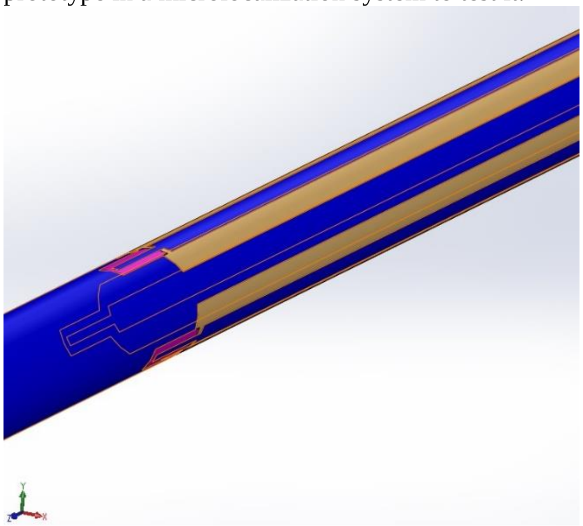


Figure 16: A needle with three microgauges at 120°

VIII - ACKNOWLEDGMENT

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