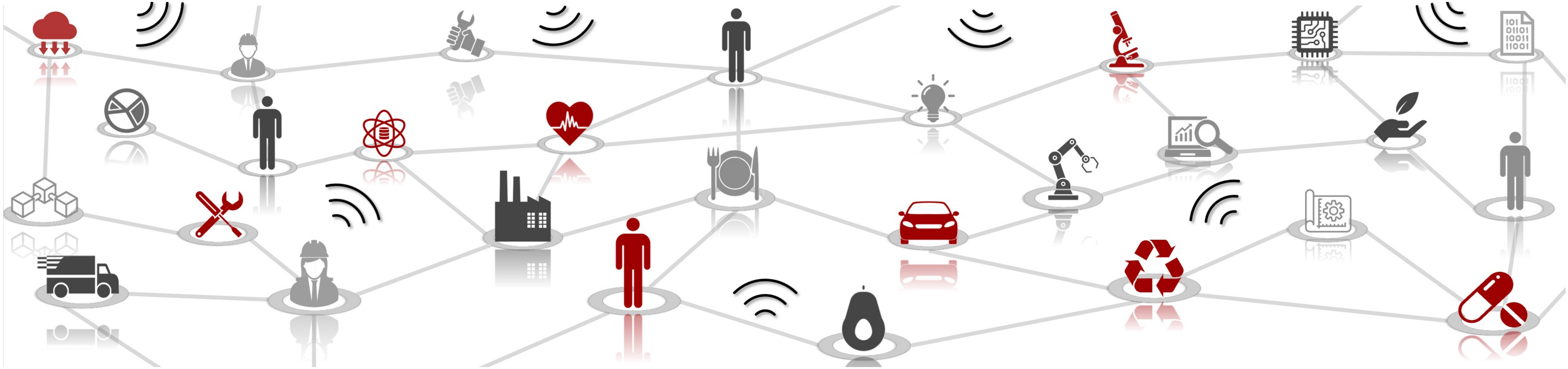


# Antennification of Implanted Orthopedic Prostheses for Early Detection of Deep Infections

*SIMULIA Regional User Meeting – EuroMed*

Dr. Carolina Miozzi

June 20th 2023

RADIO6ENSE
The last meter of Internet of Things

DASSAULT SYSTEMES

# I introduce myself…

**Dr. Carolina Miozzi**, Ph.D.

System Engineer in RADIO6ENSE srl

Co-author of > 25 publications
Co-inventor of 3 Patents

Oct. 2016
*Join the LEP as Master Student*

Apr. 2017
*Master Degree in Medical Engineering*

*First collaboration with RADIO6ENSE*

Nov. 2017
*Ph.D. in Electronics Engineering*

Sept. 2019
*Part-time with RADIO6ENSE*

2021
*Doctor of Philosophy*

*Full-time with RADIO6ENSE*

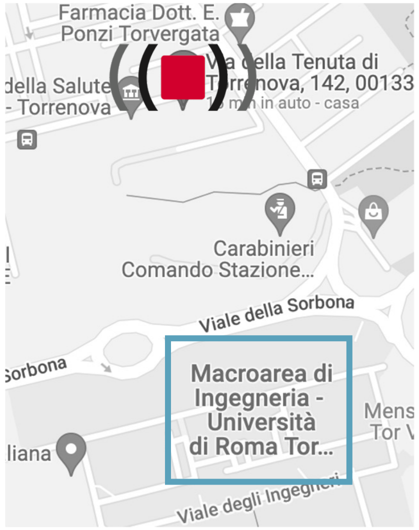
TOR VERGATA
UNIVERSITÀ DEGLI STUDI DI ROMA

Faculty of Engineering

Pervasive Electromagnetics Lab
Università di Roma Tor Vergata

A Spin-off of the University of Roma Tor Vergata
RADIO6ENSE
The last meters of Internet of Things
www.radio6ense.com

RADIO6ENSE's new Office, 2021

# RADIO6ENSE

## The ~~last~~ first meter of Internet of Things

### Innovation

R6E is a reliable partner for Open Innovation about wireless and battery-less RFID sensor technologies

### Development

R6E develops added-value and customized solutions based on the paradigms of Internet of Things and Industry 4.0

### Deployment

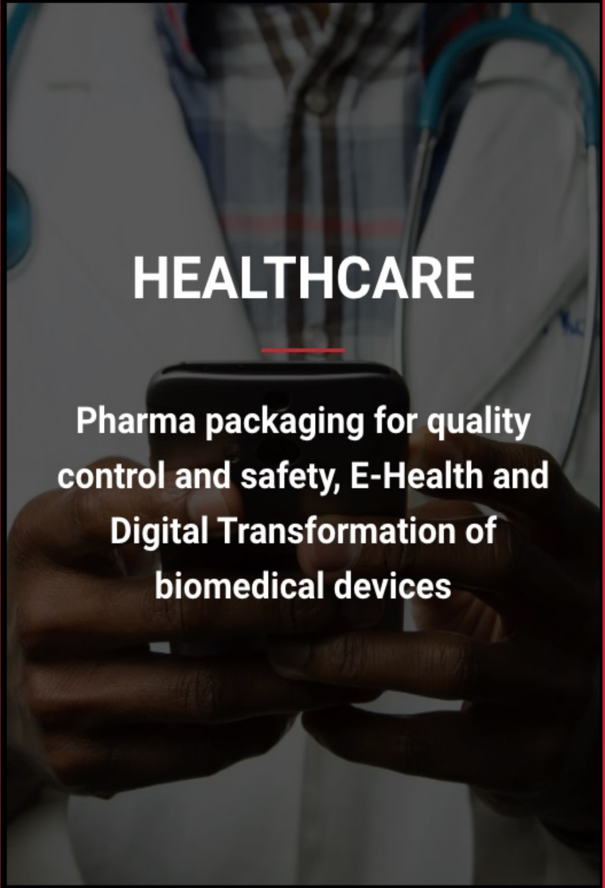
R6E takes care of the installation and commissioning of I-IoT systems, plant and/or equipment at the customer's site.

**Tomorrow, Everything will be interconnected to generate digital value**

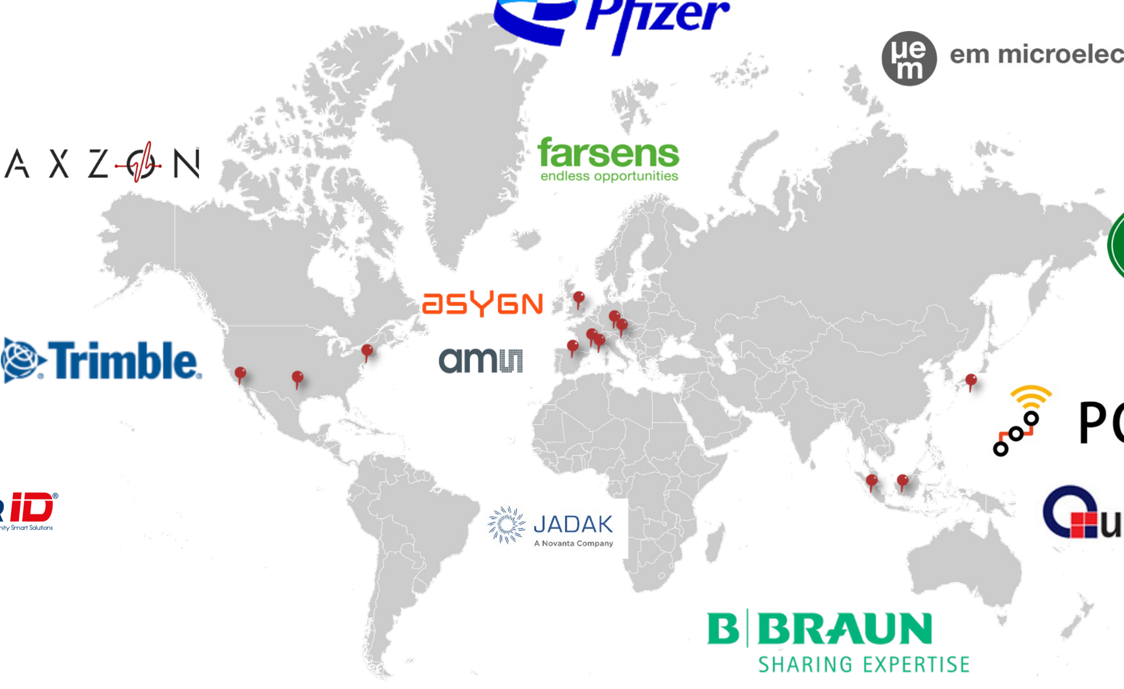
# Industry 4.0 Applications

R6E is a pioneer in the deployment of industrial RFID sensor networks



# Customers & Partners

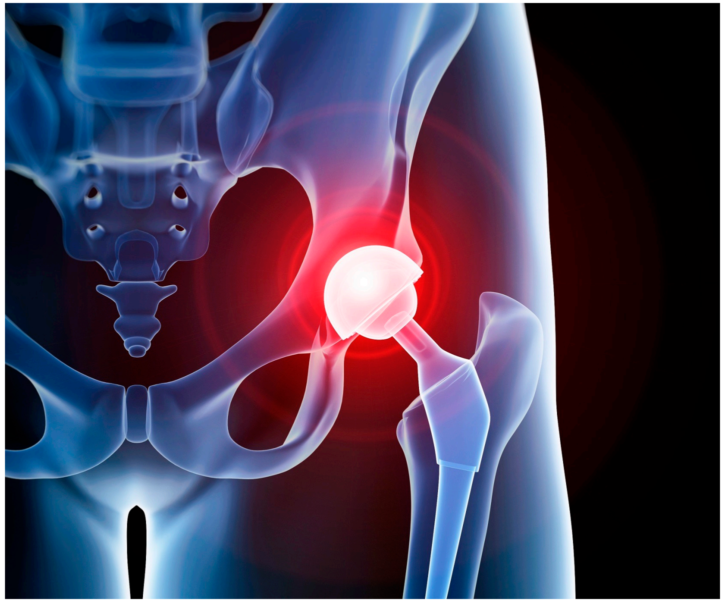



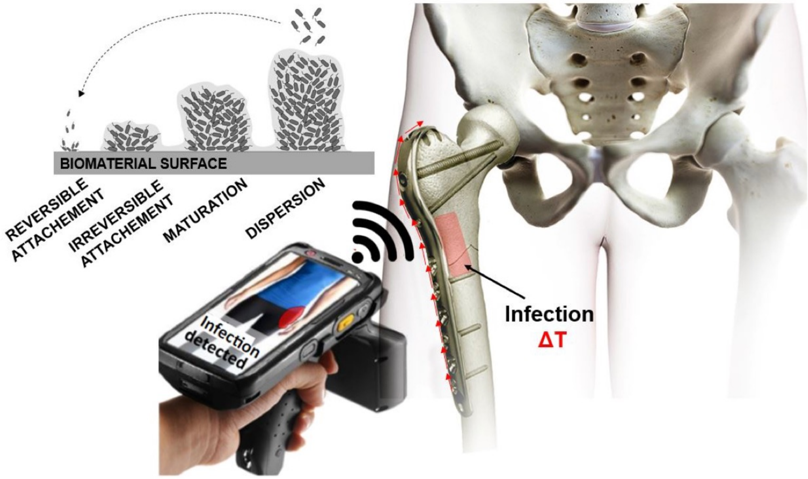

**Boosting the digital transformation**

Multinational Companies
Small Medium Enterprise
Government agencies

# Cyber Prosthesis

*From Academy... To Industry*



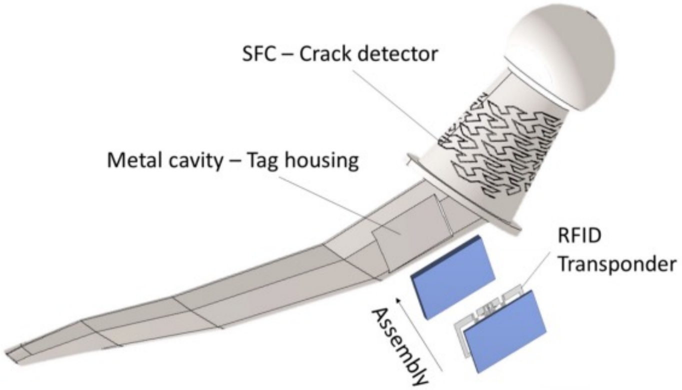



*Temperature sensor*


*Strain sensor*

Implantation of orthopedic devices or prostheses is often correlated to the risk of some complications (infections, fractures etc..)

- ➢ Detect abnormalities and warning for early intervention
- ➢ Monitoring the “Health” status of the implant




*Micro cracks detection*

Orthoload

# This work

*Early detection of deep inflammation* after the implantation of the orthopedic fixator, through the *in-situ* temperature measurement.

**Requirements:**

- No wires
- No batteries
- Minimal impact on existing devices

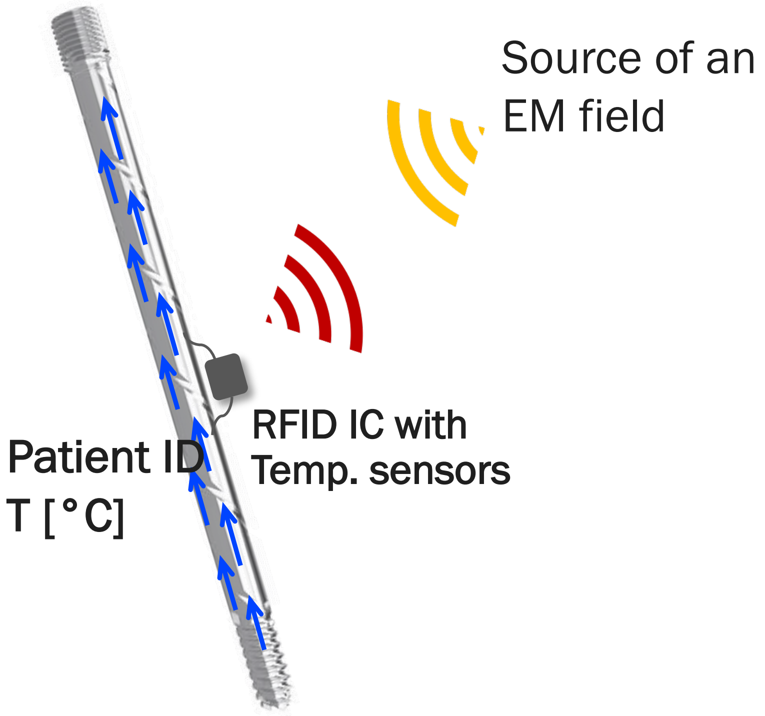
**Main Challenges:**

- High electromagnetic losses of the human model
- Small size available for sensor integration
- *Metallic prosthesis*

ORTHOFIX


**Through-the-body** wireless communication based in **Radio-Frequency IDentification (RFID) technology**

# The Challenge

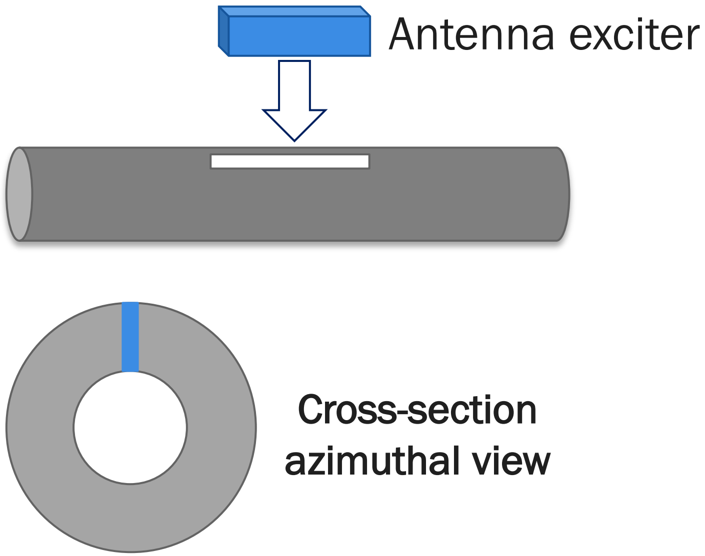



How to use these currents to power an RFID chip and enable wireless data communication?

**Structural antenna**
Minimizing modification of implant geometry

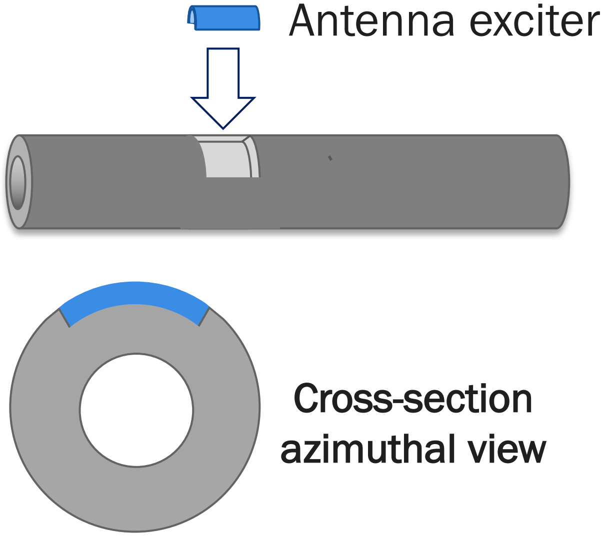
# “Antennification” strategies

## 1 *Narrow Longitudinal Cut*




Longitudinal cuts are expected to have less impact on robustness than axial cuts

## 2 *Thin Local Notch*




Azimuthal extension and depth of the notch to be discussed vs. mechanical robustness

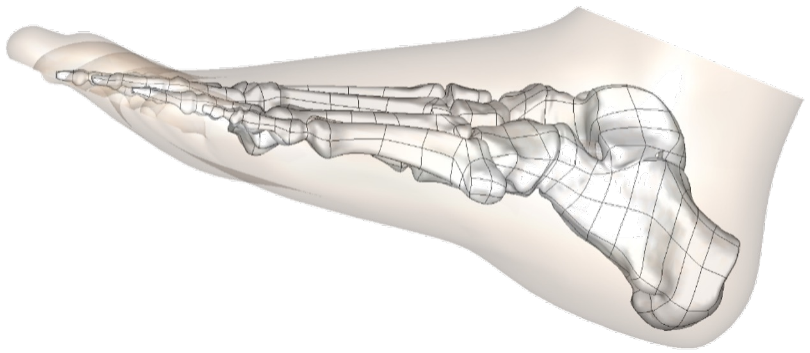
## 3 *End-Cap*


Modifying the distal part of the nail is less impact on the mechanical robustness than the core

Antenna can be embedded in the End Cap of the fixator, without any modification of the core

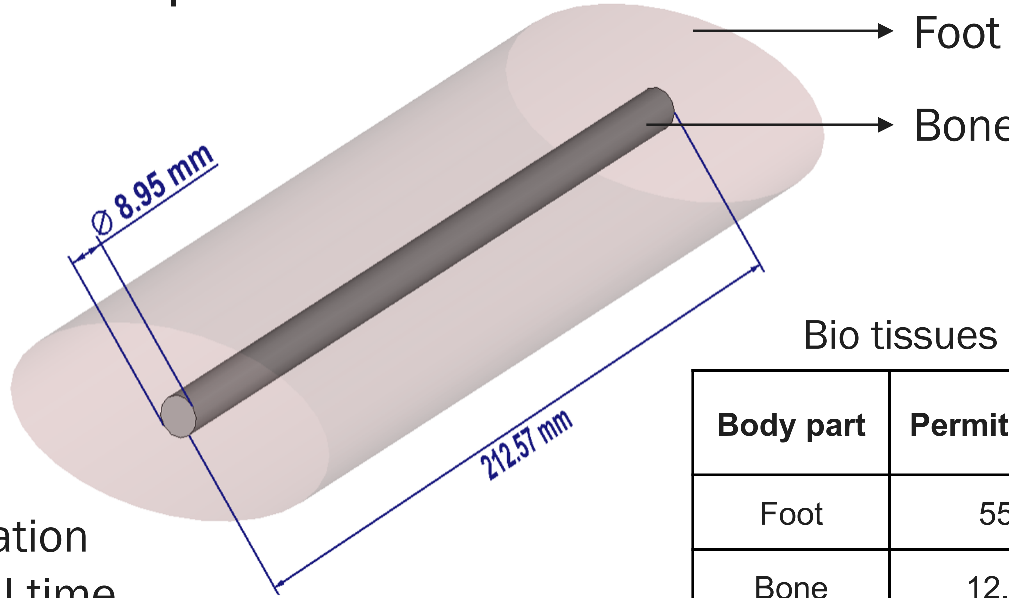
# Simplified foot model

## Realistic foot model



3D foot model simplification to reduce computational time

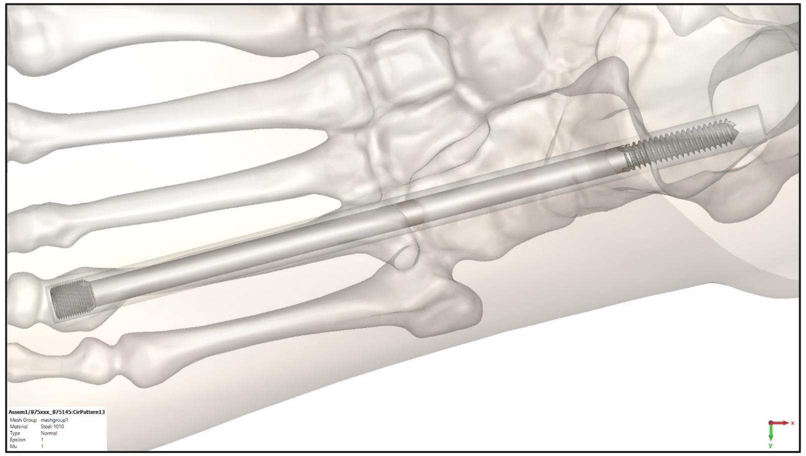
## Simplified foot model



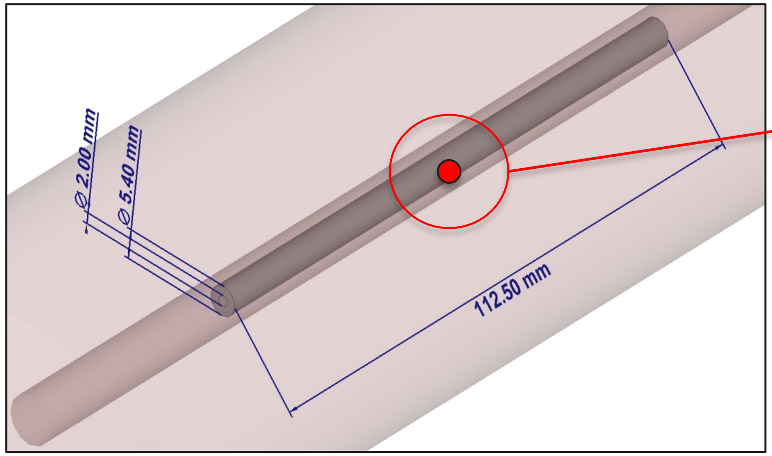

Bio tissues proprieties

| Body part | Permittivity | Tanδ (S/m) @870 MHz |
|---|---|---|
| Foot | 55 | 0.34 |
| Bone | 12.9 | 0.22 |

## Orthopedic prosthesis



## Simplified prosthesis




The port is oriented towards the long side of the foot

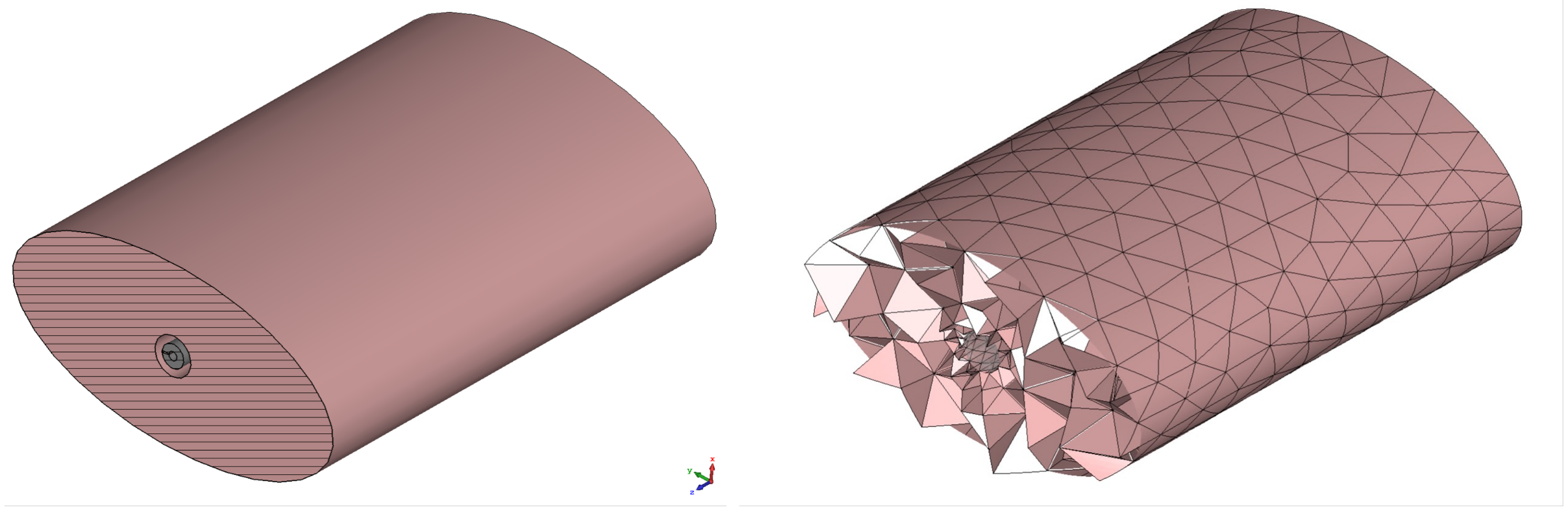
Worst case of radiation

# Design features

*Electromagnetic solver*

**CST Studio Suite** 3D Electromagnetic simulation software

**Frequency Domain Solver - Finite Element Method**



- High-frequency application
- Small – Medium-sized model
- More suitable type of mesh
- Faster multi-port analysis

# Key Performance Indicators

1. Turn-on EIRP (*Equivalent Isotropic Radiated Power*) at a fixed reader-skin distance (d=10 cm):

$$EIRP_{to} = \frac{p_{chip}}{G_A \cdot \eta_P} \left( \frac{4\pi \cdot d}{\lambda} \right)^2$$

$EIRP$: Equivalent Isotropic Radiated Power
$p_{chip}$: RF-chip sensitivity
$G_A$: **Antenna Gain**
$\eta_P$: polarization factor
$d$: Interrogator-Implant distance
$\lambda$: wavelength

- Readable by fixed readers
- Readable by mobile readers
- Not readable

2. Impedance matching capability:

   - Low
   - High

Antenna impedance should be matched with the load impedance, i.e. the RFID microchip $Z_{IC} = 2.8 - j76$ [Ω]

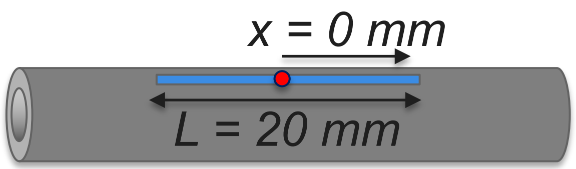
3. Impact of geometric changes of the existing implant *p*:

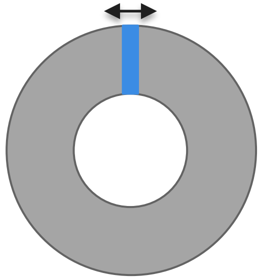
   - Negligible
   - Moderate
   - Huge

$EIRP_{to}(p)$

Note: The numerical analysis was performed considering the worldwide UHF band 860-960 MHz (900 MHz center frequency)

# Narrow longitudinal cut



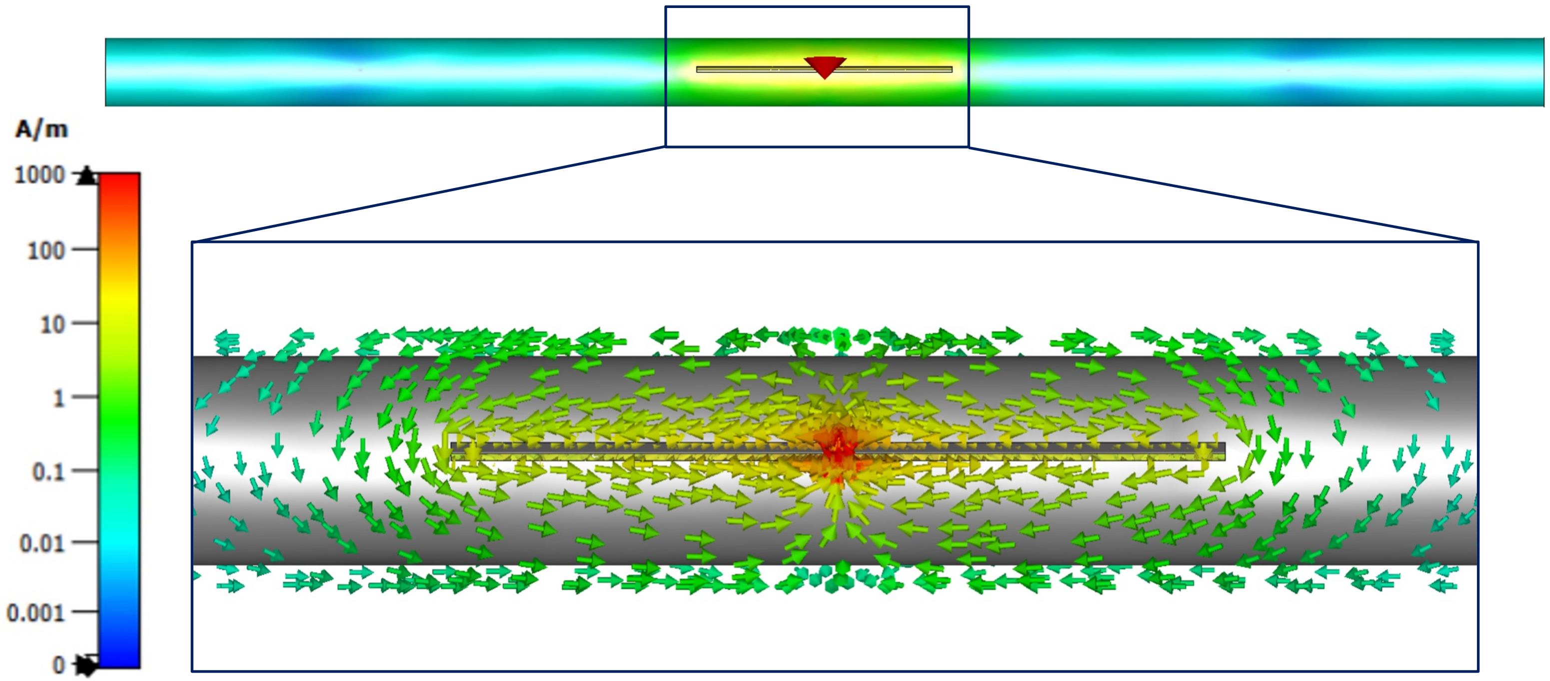




*Slot Antenna*

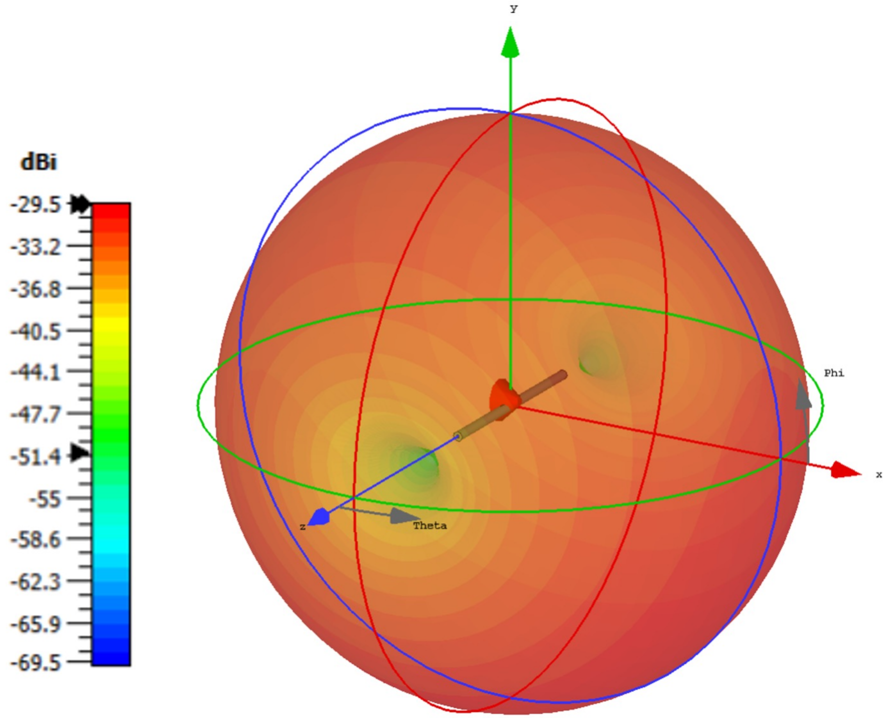
**Geometrical parameter *p*:**

- *L:* Length of the strip
- *x*: feed point position

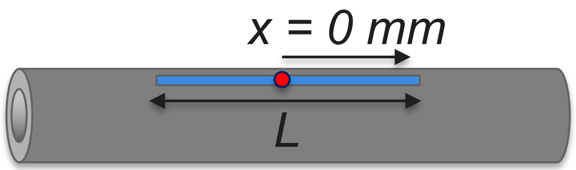
Currents distribution @900 MHz



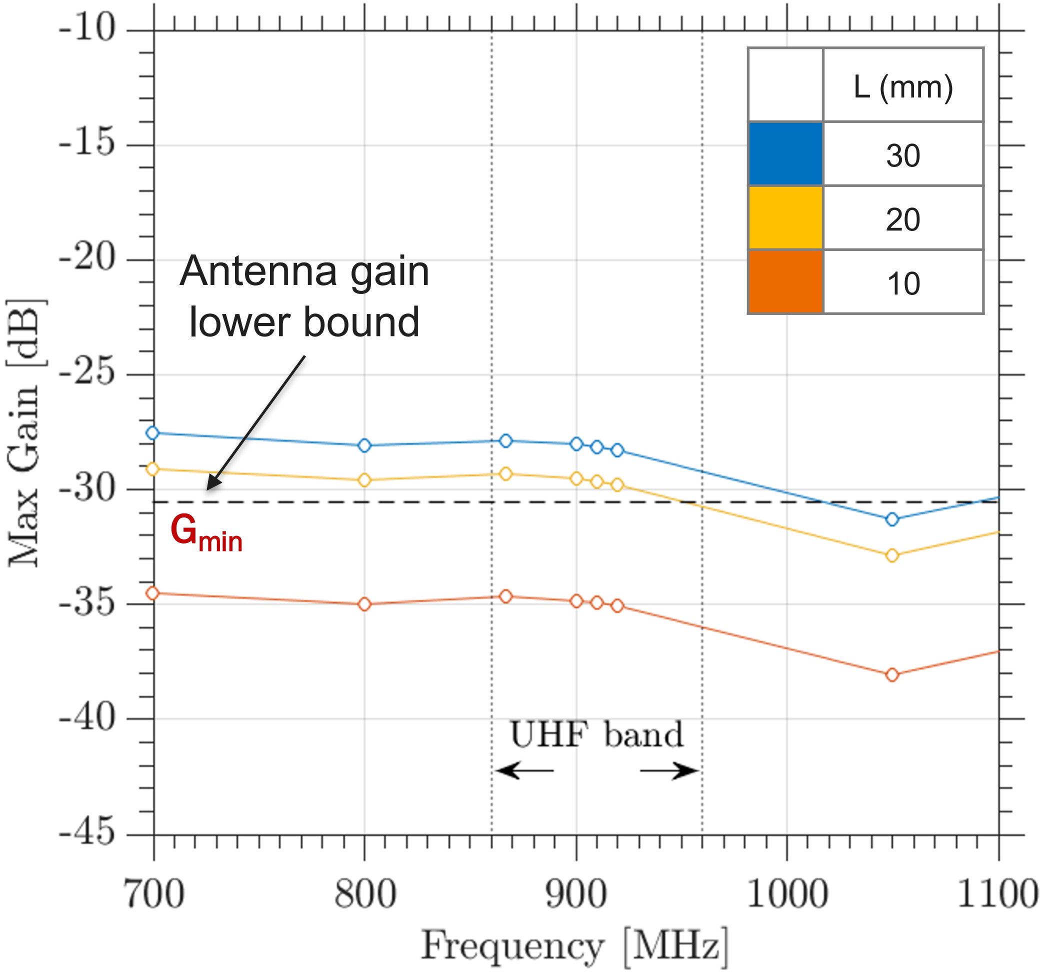

Radiation pattern @900 MHz

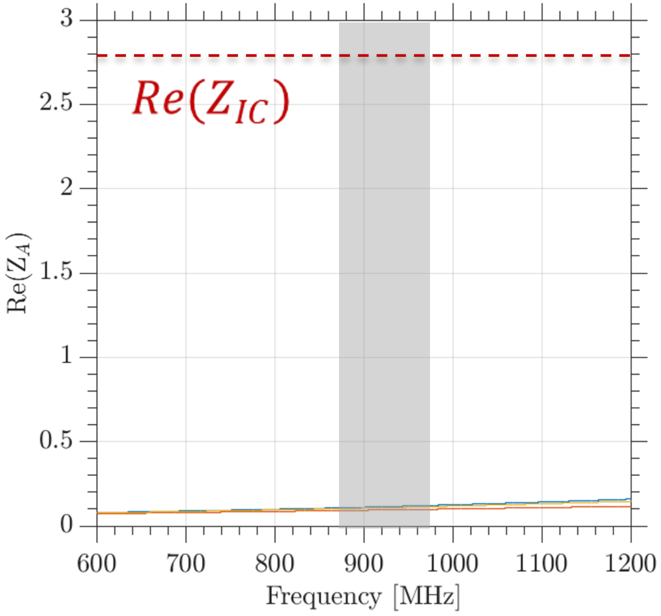


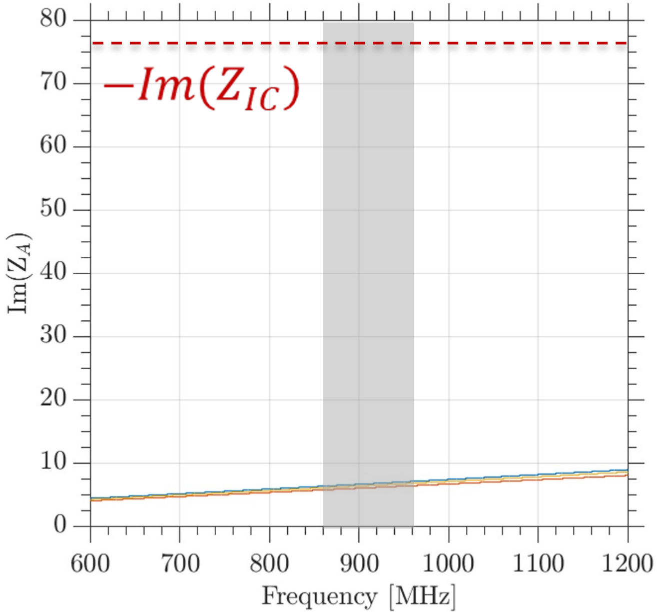
# Narrow longitudinal cut




*Parameter sweep on the L length of the slot*



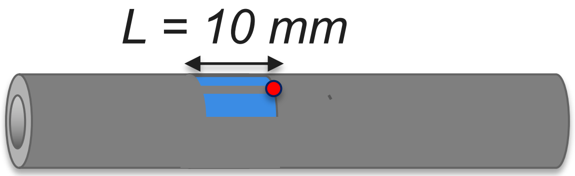

Small values of antenna impedance:

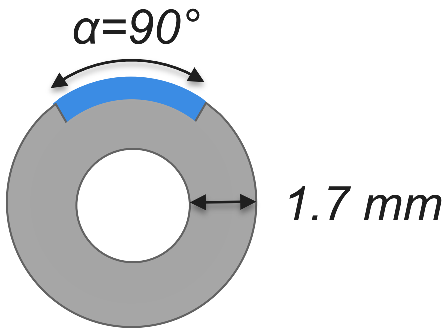
→ Low impedance matching capability

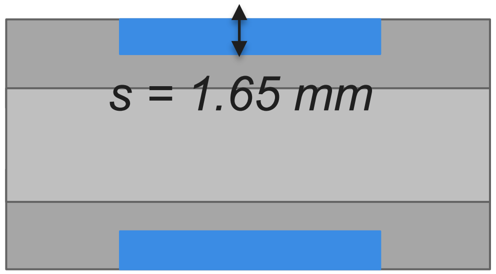
→ The antenna needs an impedance matching circuit

# Thin Local Notch

## *Γ – match Dipole Antenna*



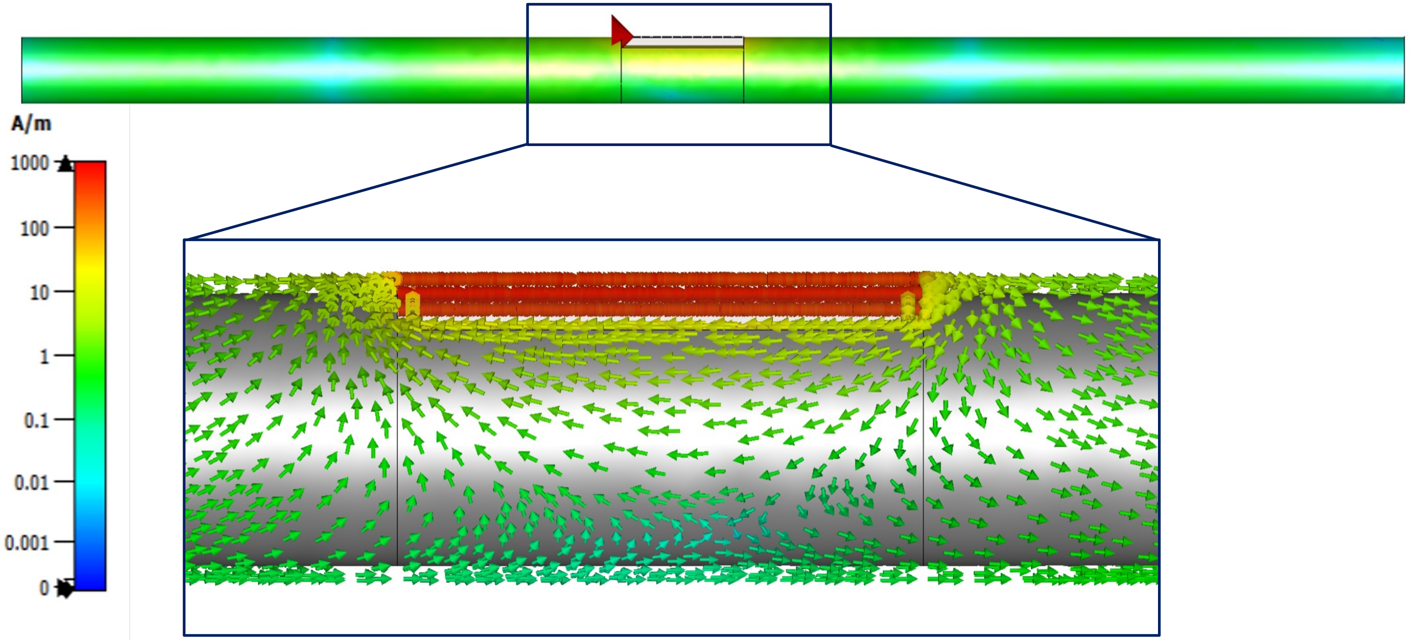



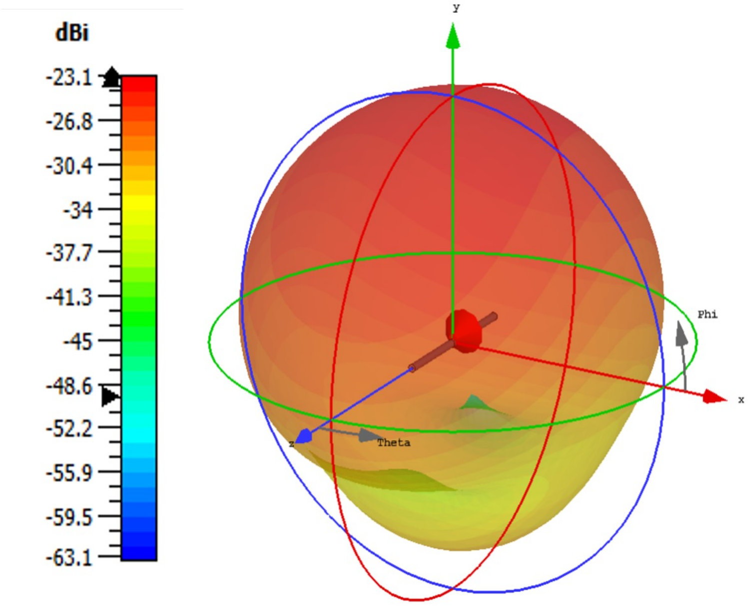

**Geometrical parameter *p*:**

- *L:* Length of the strip
- *α*: angle of the notch
- *s:* thickness of the notch

Currents distribution @900 MHz

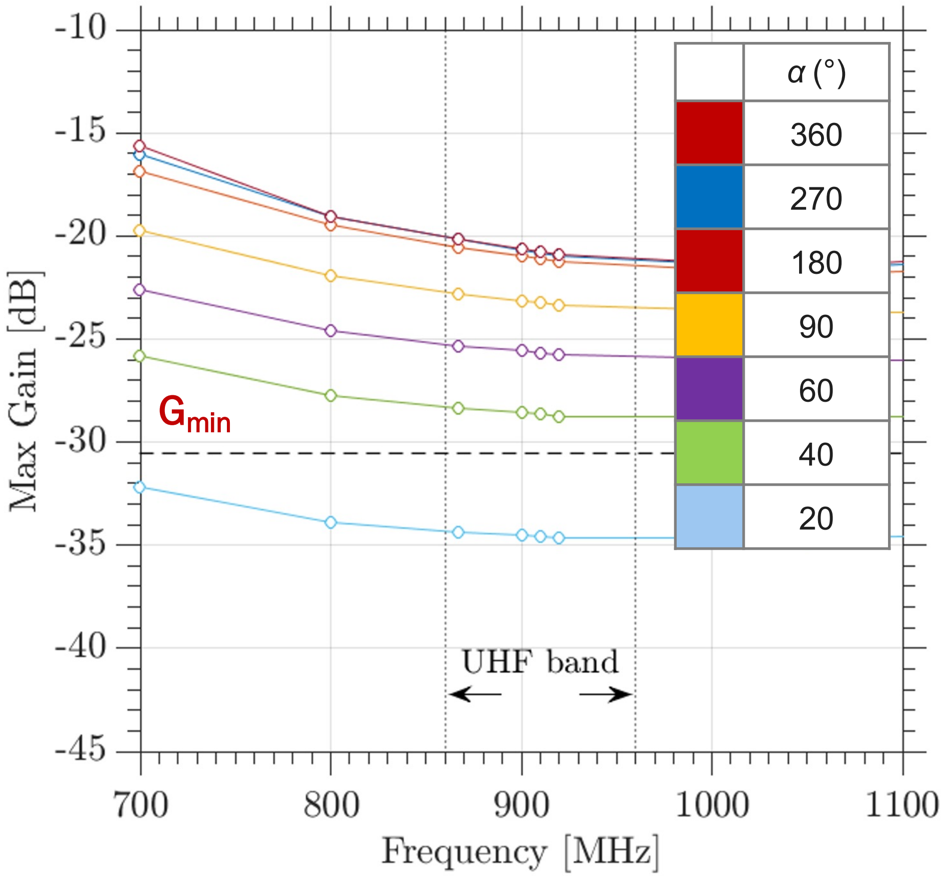


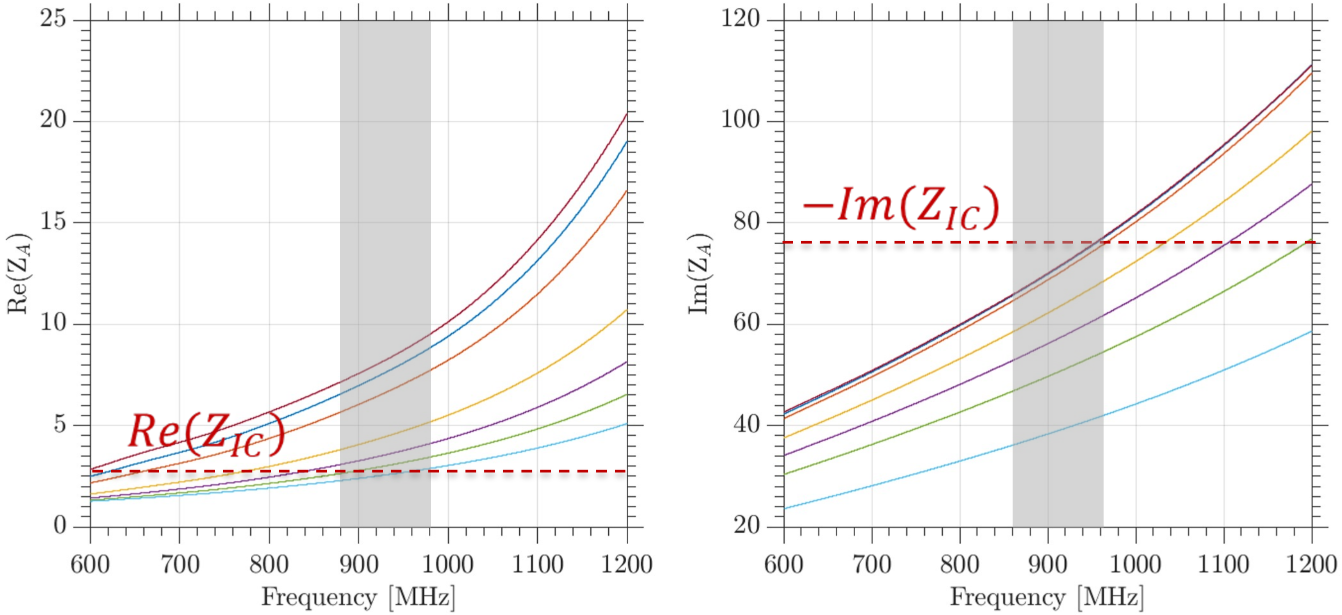

Radiation pattern @900 MHz



# Thin Local Notch


*Parameter sweep on the angle of the local notch*

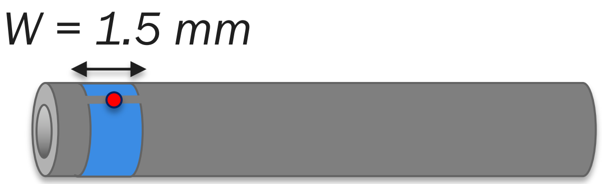



The antenna impedance can be **matched** with the chip impedance, both for the real and imaginary part

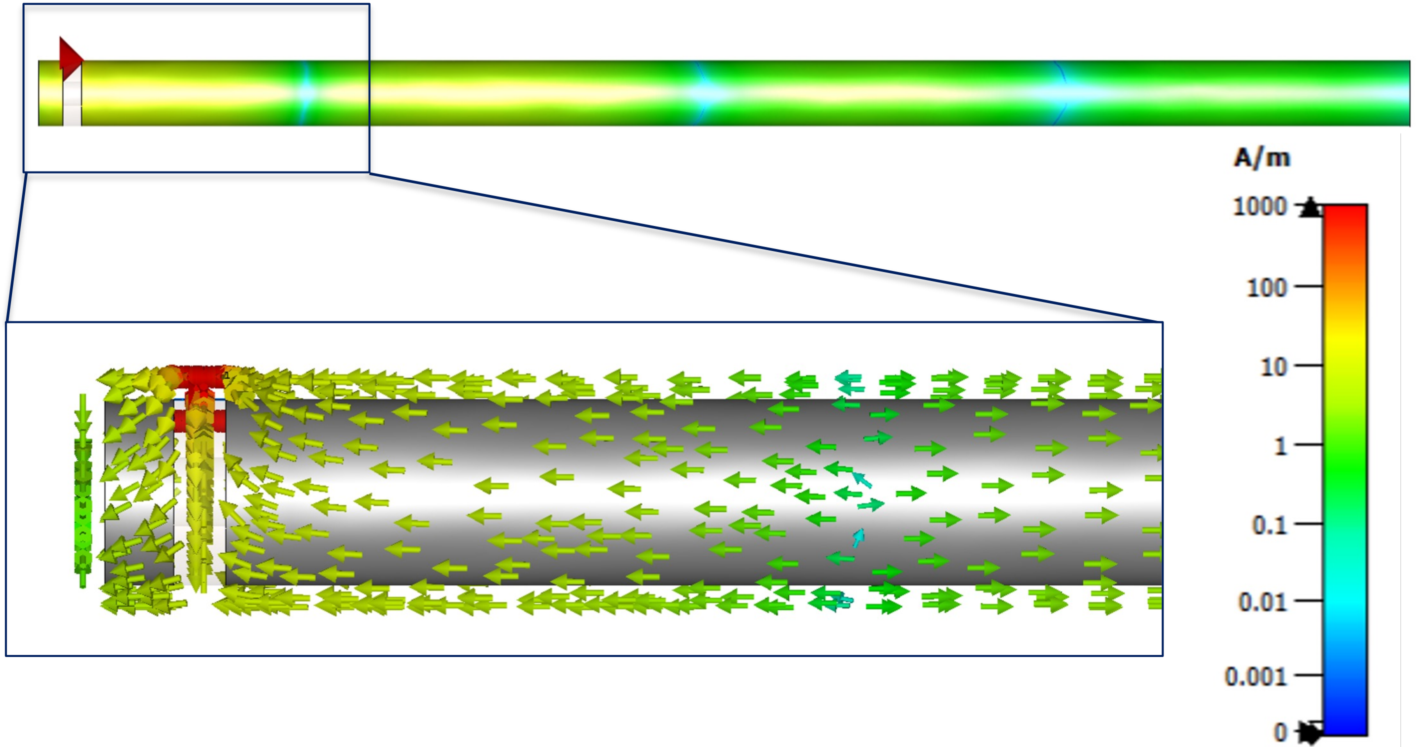
# End Cap

*Asymmetric Dipole Antenna*

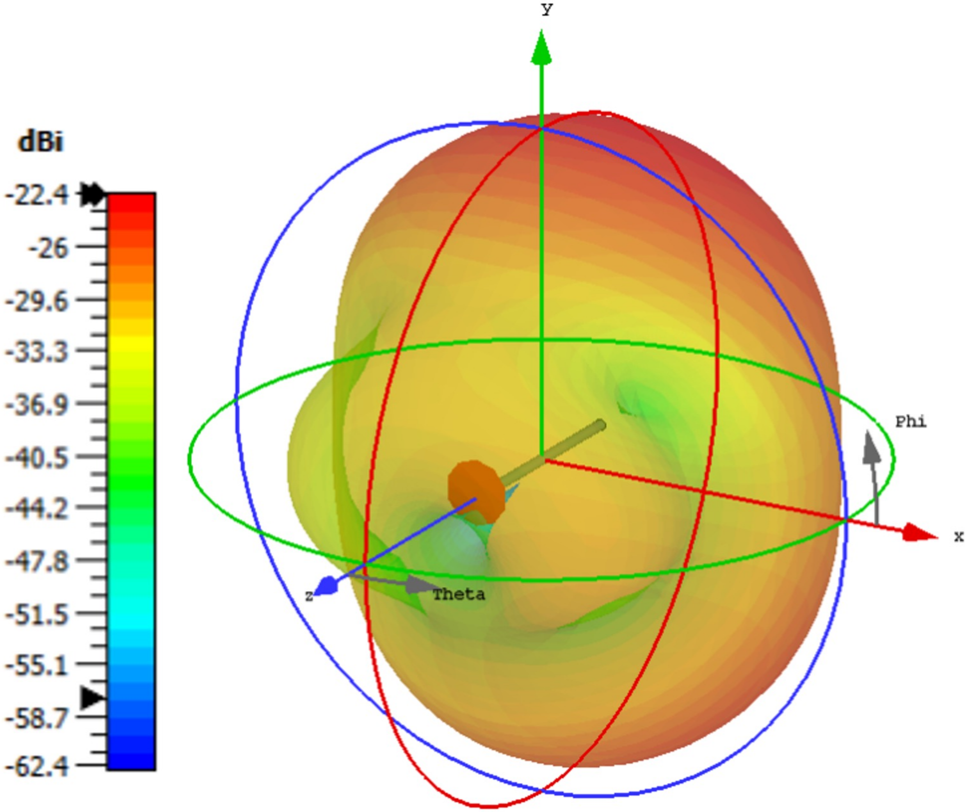



**Geometrical parameter *p*:**
*W:* Width of the dielectric

Currents distribution @900 MHz

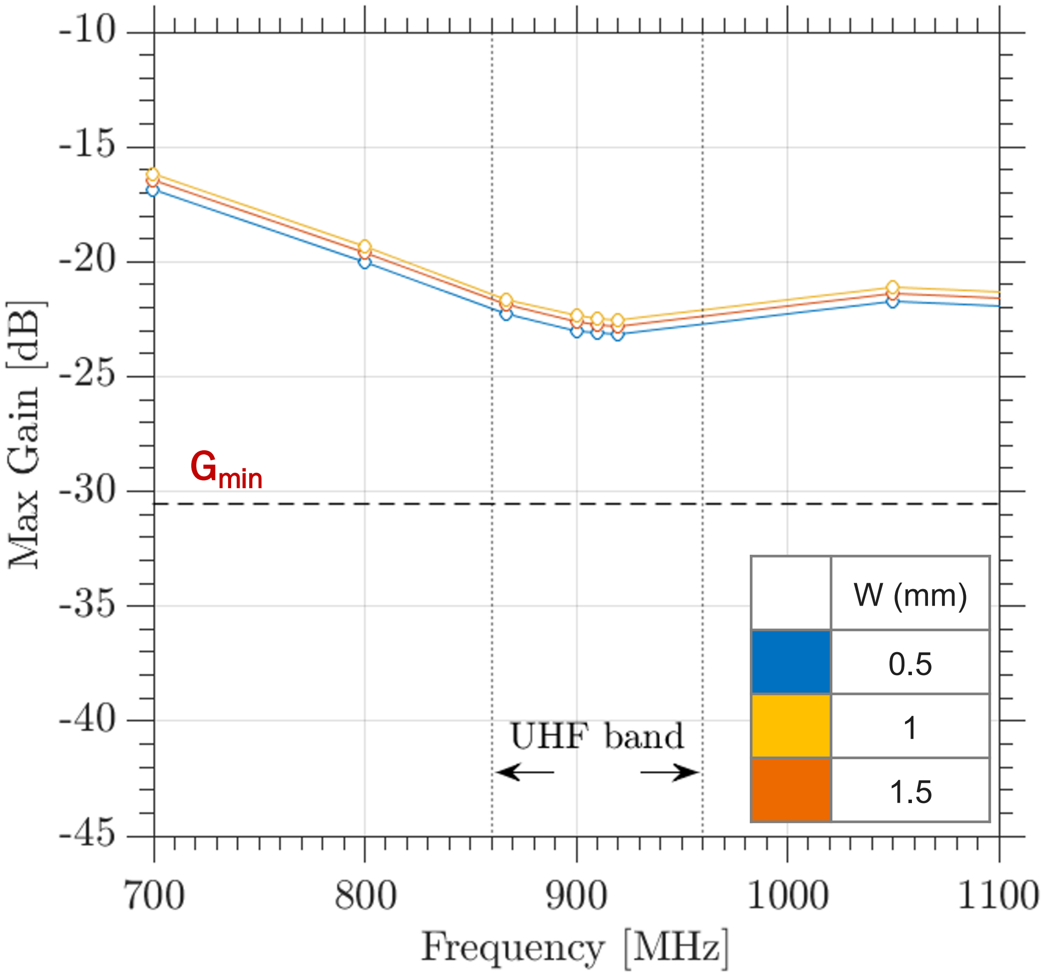


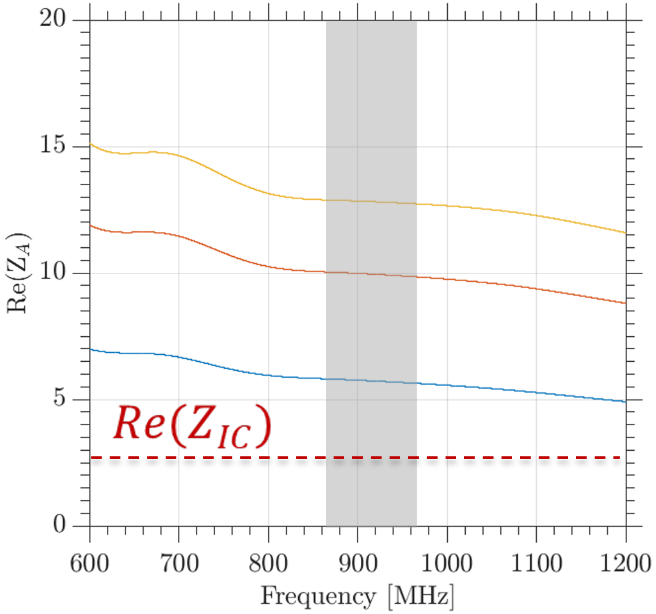

Radiation pattern @900 MHz

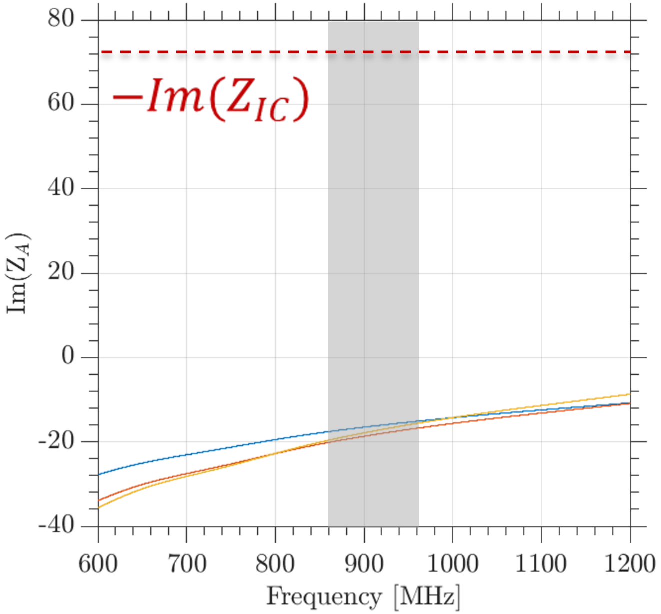


# End Cap


*Parameter sweep on the width of the dielectric*



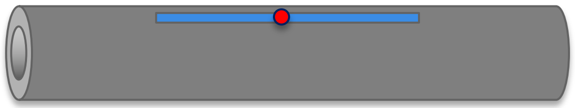



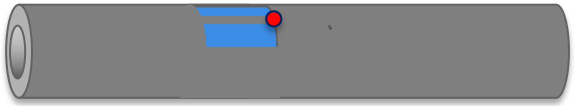




The impedance of the RF chip is capacitive so that for achieving the antenna-chip impedance matching, the imaginary part of the antenna impedance must be positive → a **tuning circuit in series with the feed** (i.e. the IC) can be used

# Summary

| Configuration | Turn on EIRP (W) (< 3.2 ) | Matching capabilities | Required changes on the existing implant | Mechanical impact |
|---|---|---|---|---|
| *Cut – Slot antenna* | 2.0 < EIRP < 2.8 | Low | Vertical full etching | High |
| *Notch – Γ – match dipole antenna* | 0.4 < EIRP < 2.2 | High | Sectoral etching | High |
| *End cap – Asymmetric dipole antenna* | ~0.6 | Need a tuning circuit in series with the IC | Extra plug-in cap | Negligible |

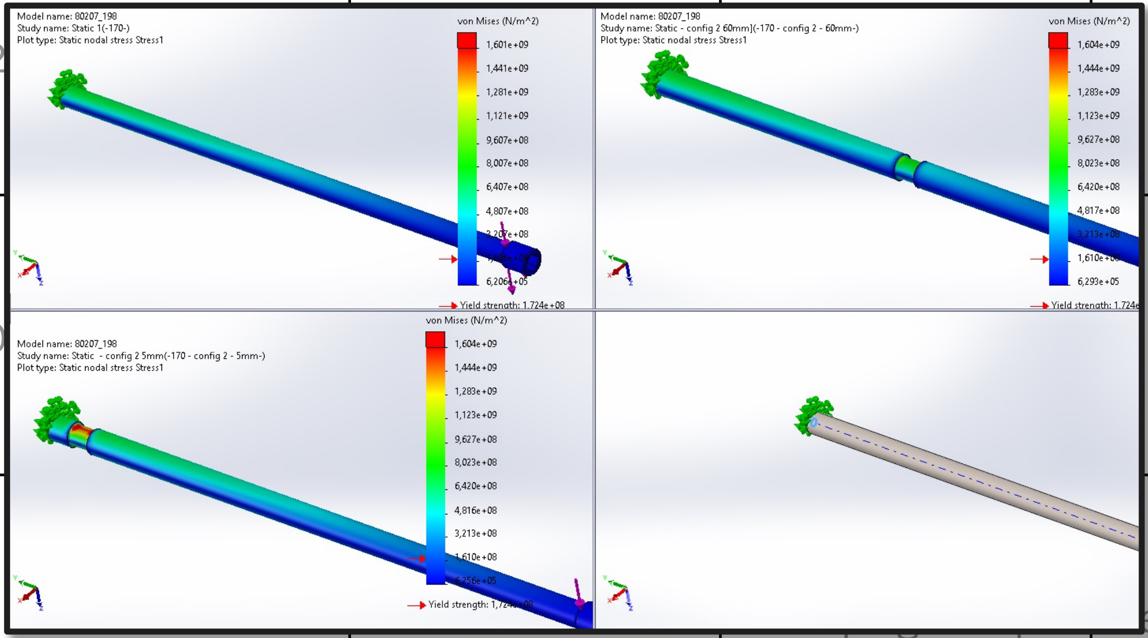


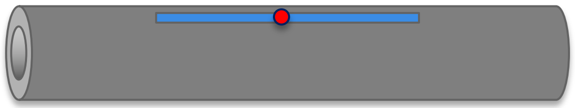


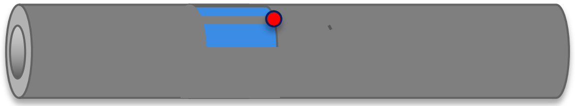
# Summary

| Configuration | Turn on EIRP (W) (< 3.2 ) | Matching capabilities | Required changes on the existing implant | Mechanical impact |
|---|---|---|---|---|
| *Cut – Slot antenna* | 2 | | | gh |
| *Notch – Γ – match dipole antenna* | 0 | | | gh |
| *End cap – Asymmetric dipole antenna* | | with the IC | | egligible |

**Mechanical numerical analysis**



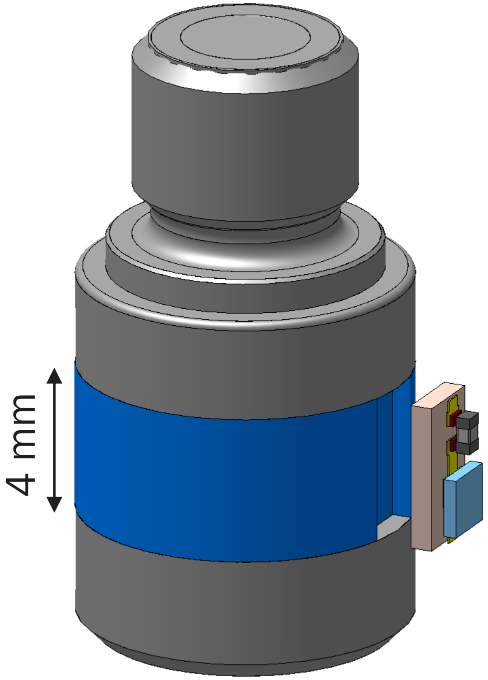



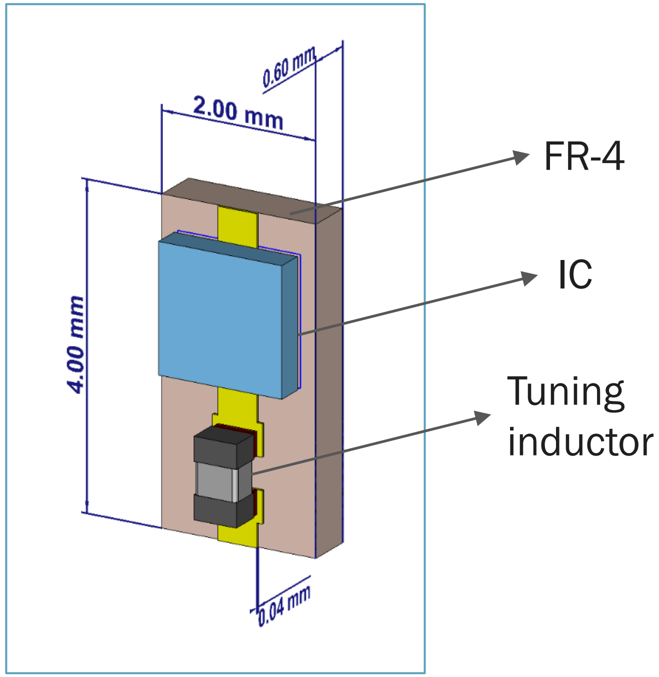


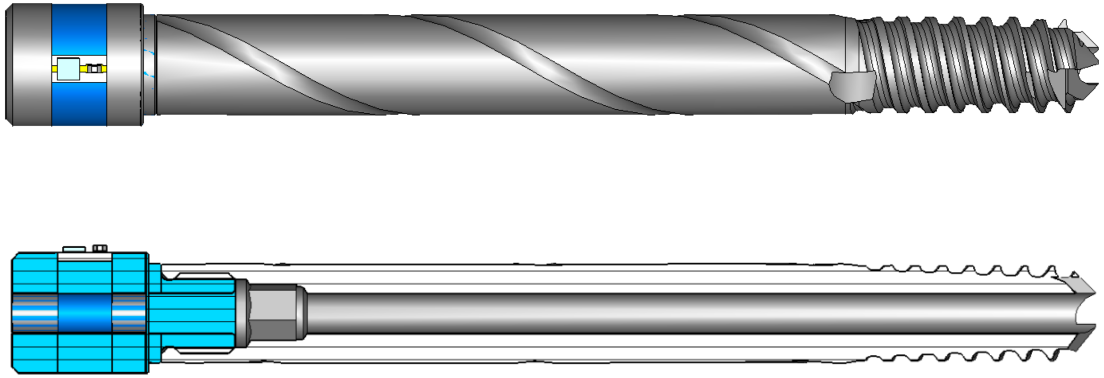
# From simplified... to realistic model

*3D CAD*

- A more realistic 3D CAD of the device that will be built was designed in order to better compare simulations with the next EM measurements.
- The first prototype of end cap will be manufactured by modelling a small PVC tube, by metalizing its surface with a conductive ink and by embedding the PCB with the IC and the inductor in a customized notch.



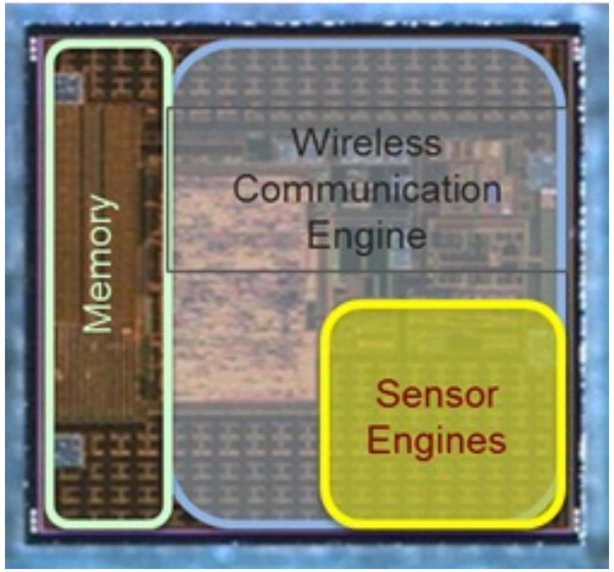



# Design features

*RFID microchip with Temperature sensor*

AXZON
SENSING DATA INSIGHTS

**Magnus® S3**




## Wireless Passive Sensor IC

***Chip Impedance***

$Z_{IC} = R_{IC} \| \frac{1}{j\omega C_{IC}} = 2.8 - j76 \, [\Omega]$

(@ 870 MHz)

***Chip Sensitivity***

$p_{chip} = -12.6 \, [\mathrm{dBm}]$

(considering the temperature data retrievement)

***Temperature sensor***

Resolution: $\Delta t = 0.13 \, [°]$

Range: -40° - 85°

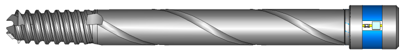
***Chip Size***

QFN: 1.6 x 1.6 x 0.35 $mm^3$

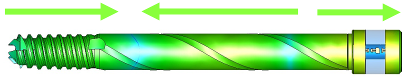
DIE: 0.94 x 0.76 x 0.15 $mm^3$

# Realistic model

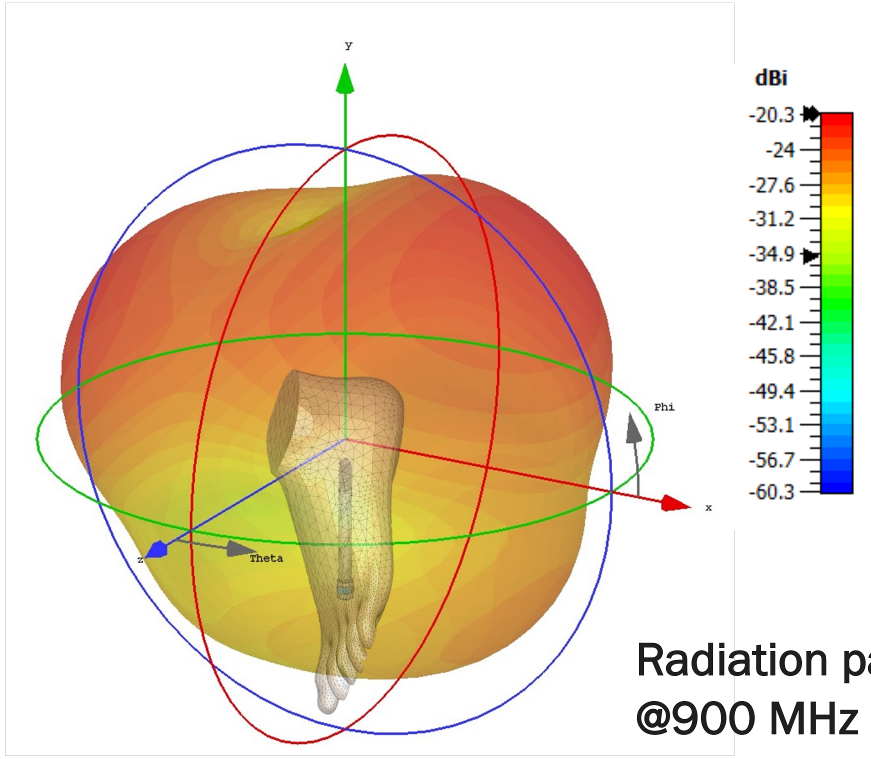
*EM Results*



Unbalanced dipole

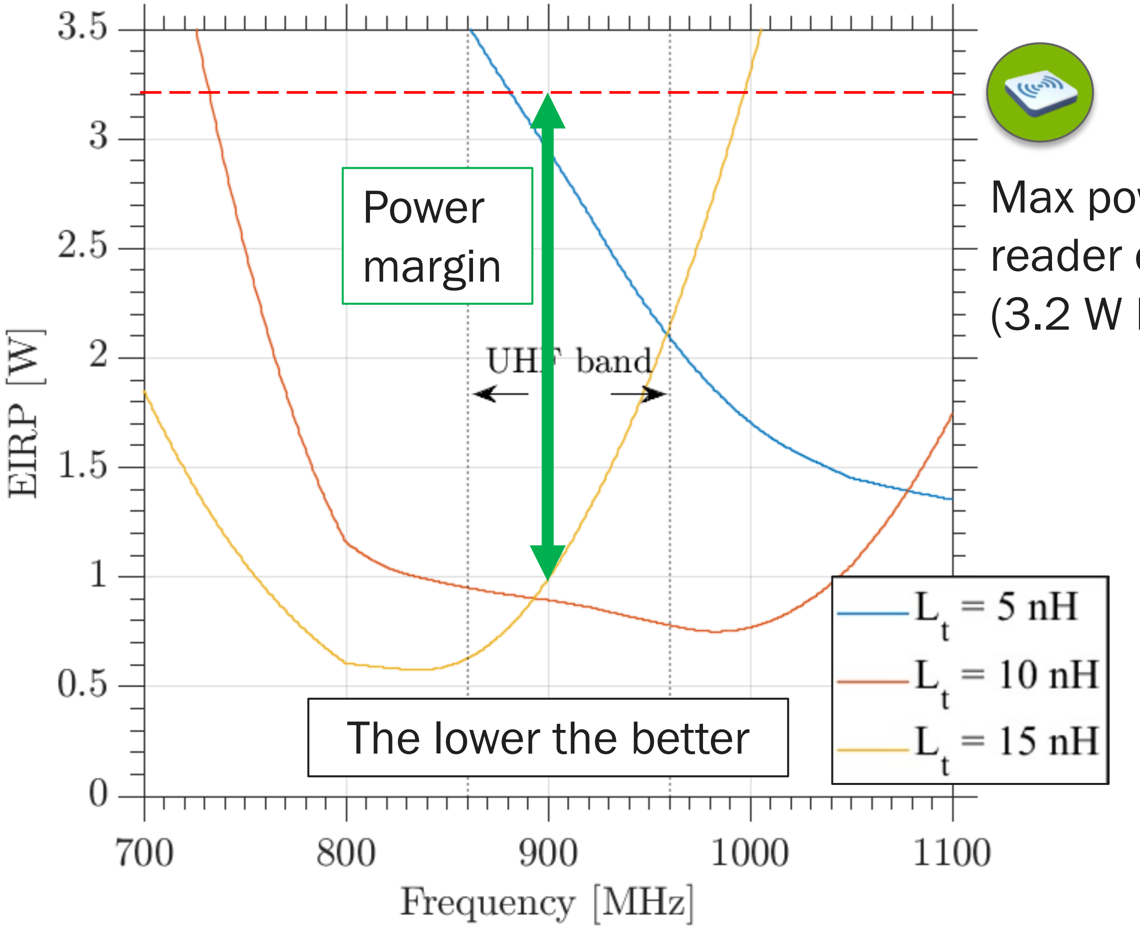


Currents distribution




Radiation pattern @900 MHz

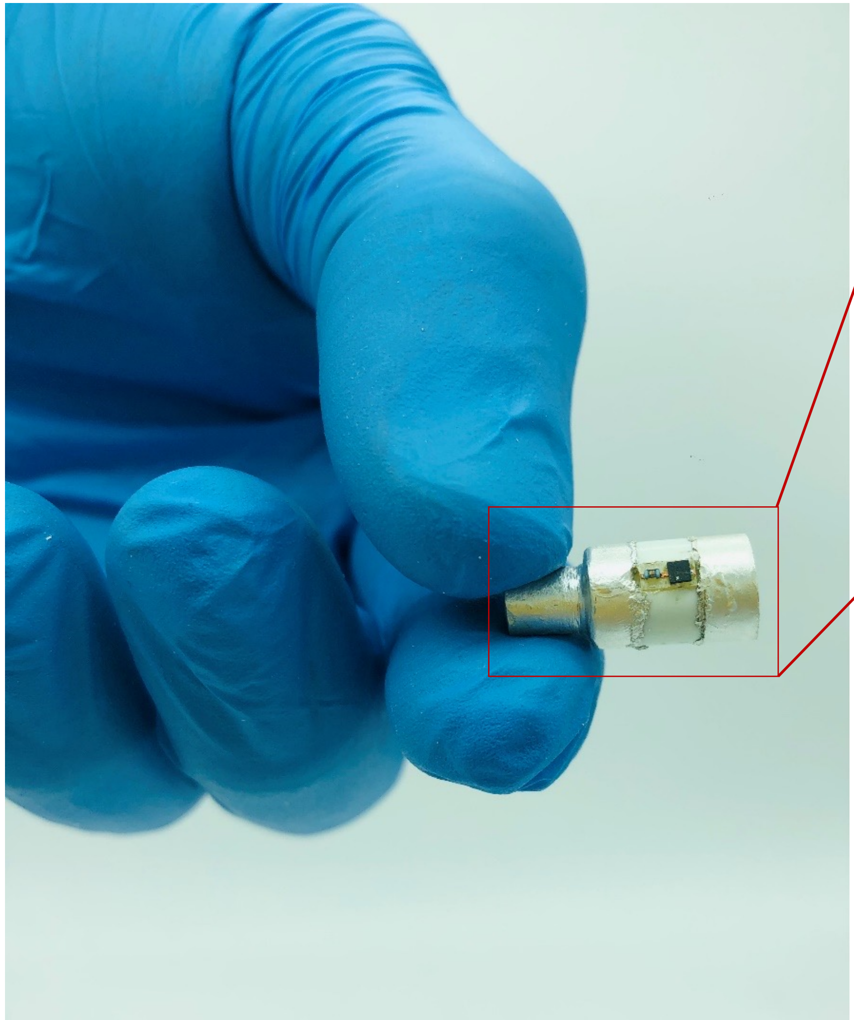
Turn-on EIRP by varying the tuning inductor

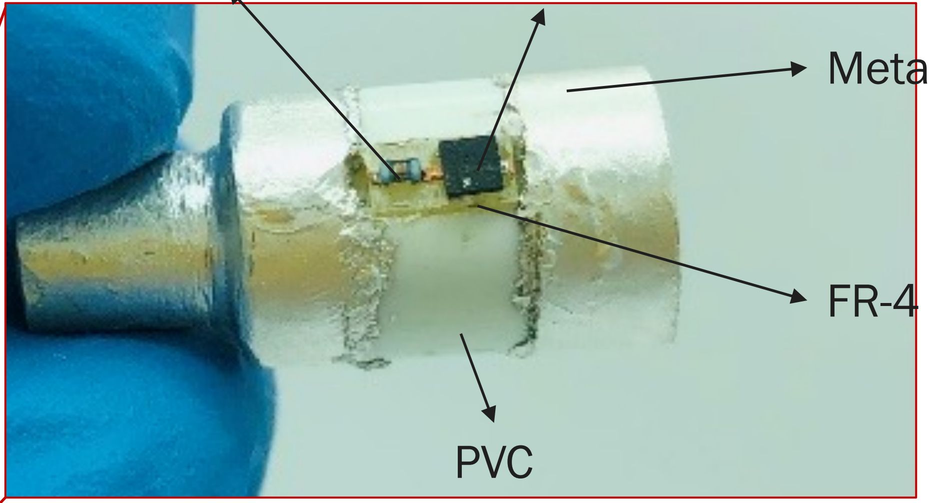



Max power UHF reader can emit (3.2 W EIRP)

# FROM SIMULATIONS TO MEASUREMENTS

# Prototyping



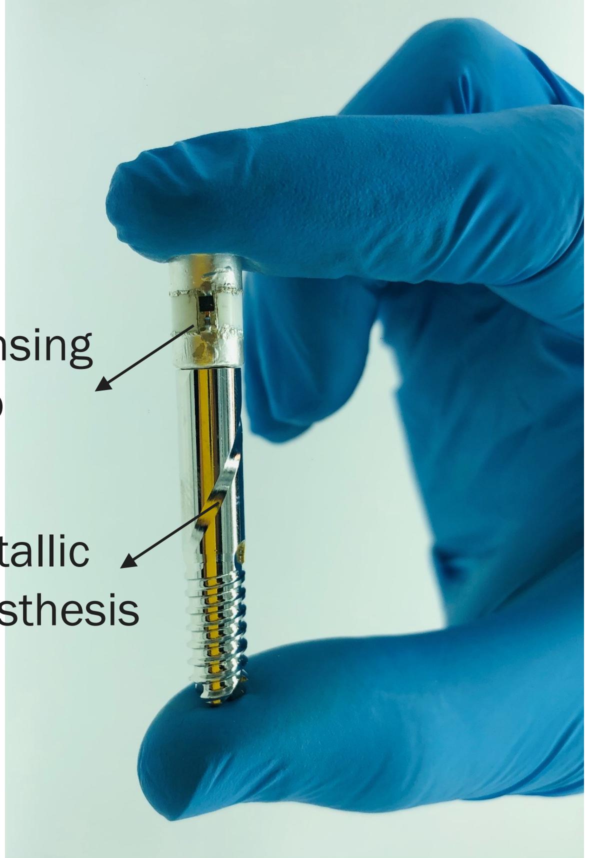


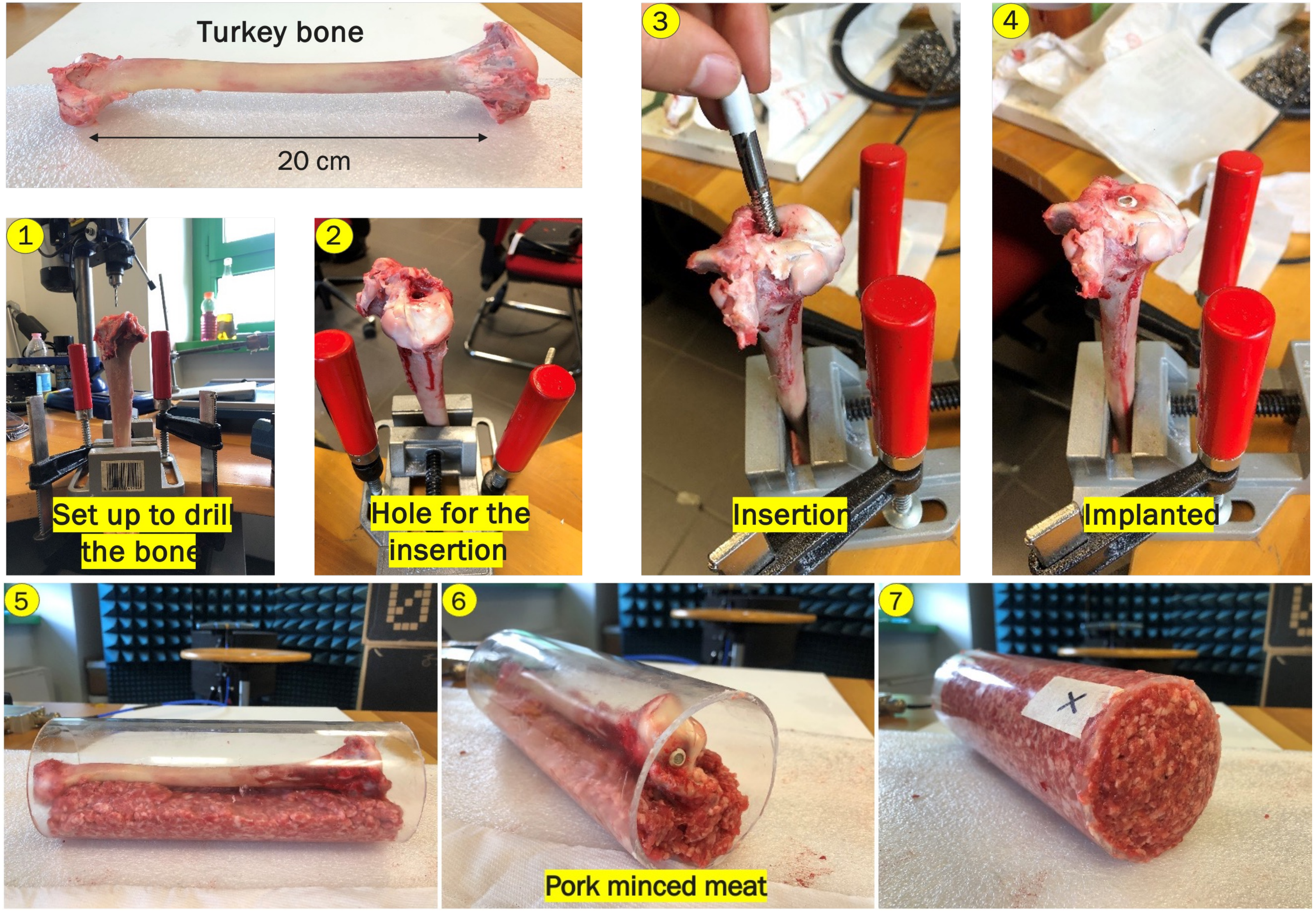

Mipec 4MILL300ATC

SMD manipulator Mipec 4PLACE

# Realistic Mock-up

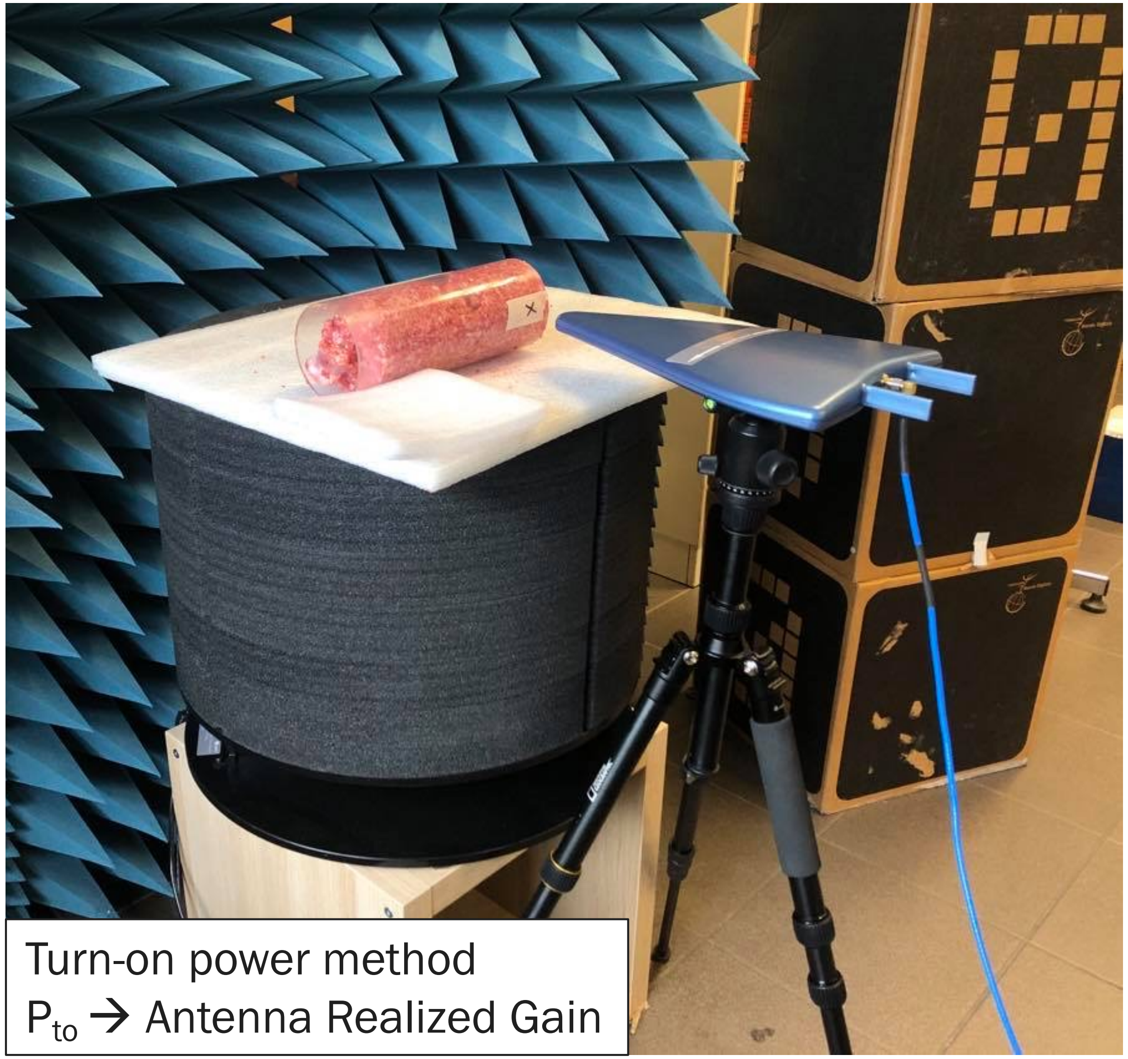
**Realistic mock-up** of the foot where the prosthesis will be realistically implanted to perform EM and temperature characterization



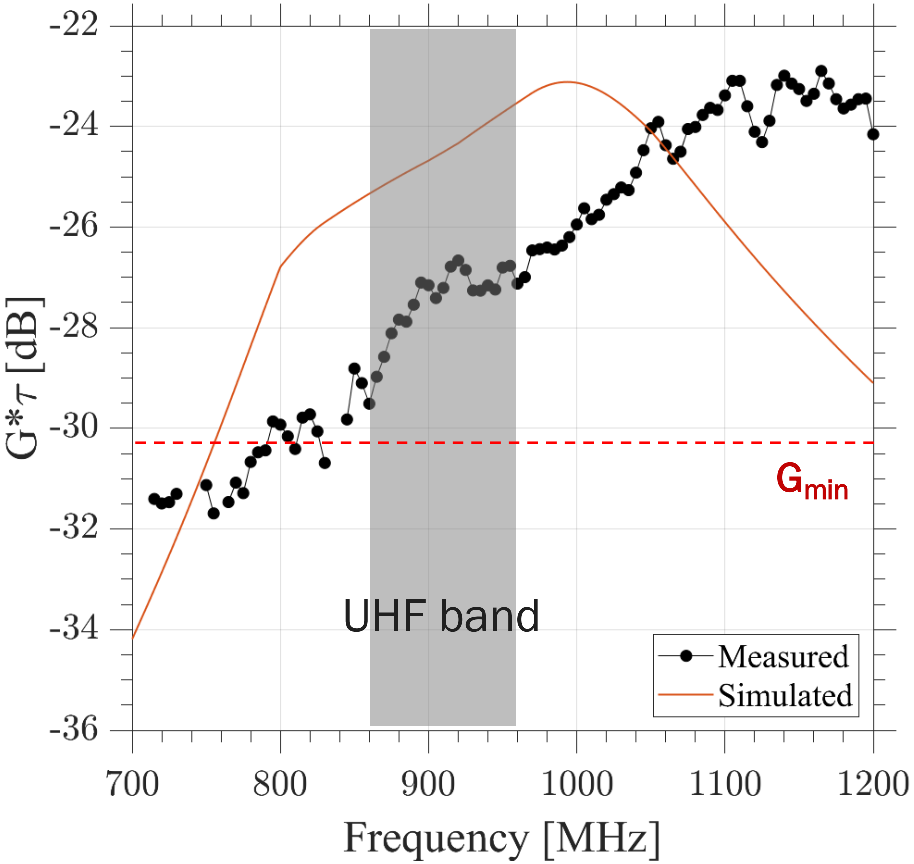



# Electromagnetic characterization

Voyantic Tagformance measurement station



Turn-on power method
$P_{to}$ → Antenna Realized Gain



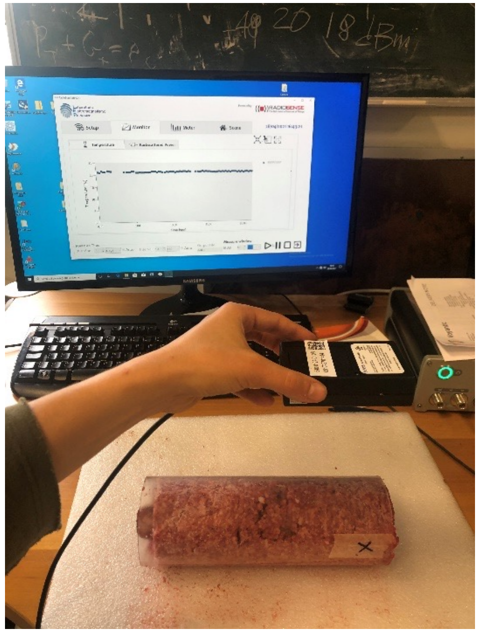

Good accordance between measurements and simulations despite a frequency shift, that can be adjusted through the tuning inductor

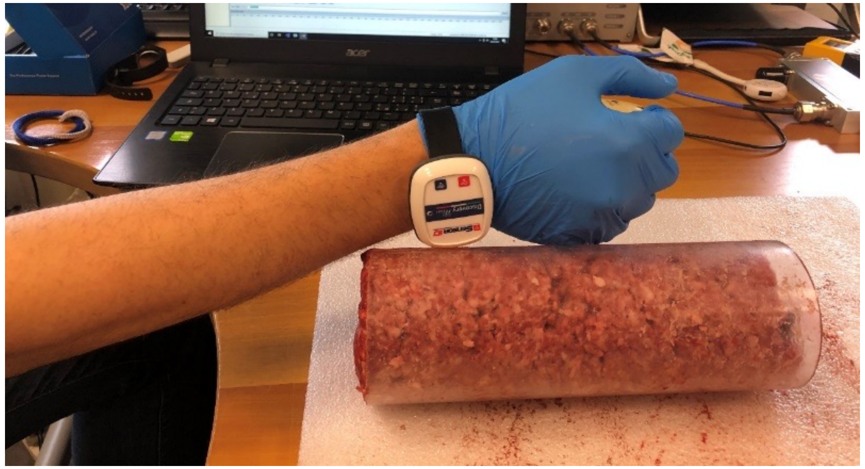
# Functional Proof of Concept

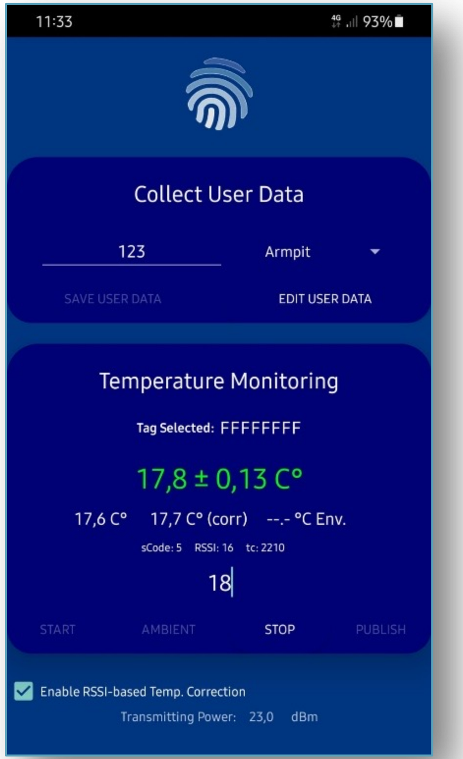
Software and visualization interface

Reader USB Pro ThingMagic

Mock-up of the foot with the implanted prosthesis







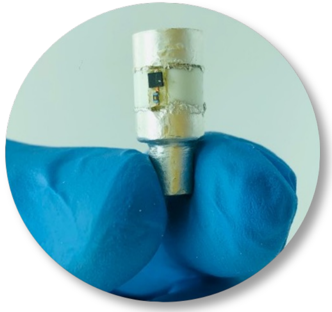
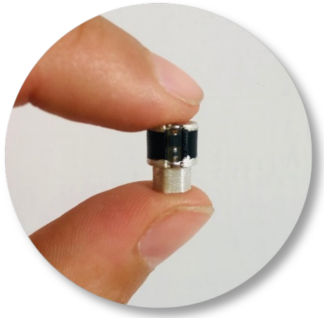
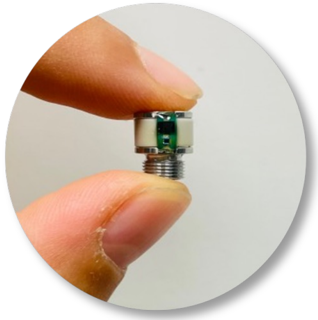

Mobile phone application

*T (°C)*

**Usability tests** with different readers and customized visualization software

# Innovation Timeline

*April 2021* **PoC** → *June 2021* **Pre-Engineered** → *June 2022* **Manufacturable**

**TRL 3-4** → **TRL 7-8**

Manufacturing/Assembly procedure and Procurement of materials

Further engineering is needed to bridge the gap between *PoC* and viable manufacturable products:

- Costs,
- Materials,
- Clinical Trial,
- Certification… !

*Patent filed on Dec. 2021*

Domanda di brevetto per invenzione industriale dal titolo:

**"Componente sensorizzato per vite endossea, complessivo di vite comprendente detto componente e sistema di monitoraggio comprendente detto componente"**

A nome:

Con sede a:

* * * * *

**RIASSUNTO**

Componente (1) per vite endossea, dotato di un corpo principale (10) che supporta un'elettronica (2) comprendente almeno un circuito di emissione di segnale e almeno un sensore per l'acquisizione di uno o più parametri biofisici di un paziente, detto componente (1) essendo associabile ad una vite endossea.

**[Fig. 1]**

5 members of the Radio6ense Team in the Co-Inventors list

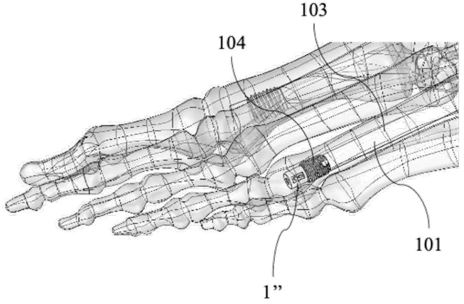



**Fig. 16**

# Take-home messages

- The use of EM simulation tools plays a crucial role in identifying the best solution for prosthesis antennification, considering the cohabitation with the human body, from the preliminary to the refined design until achieving a functional PoC of the solution

- RFID technology is enabling for the integration of sensors into objects. Typically we deal with integrated solutions, therefore multiphysics simulations are essential in our way of working

- Utilizing simulation tools that can easily interface with mechanical simulators within the same environment enables multiphysics numerical analysis, which is essential to evaluate the robustness of the solution

- The use of 3DEXPERIENCE could help speed up the numerical analysis and easily interface with the results, allowing advanced multi-physics simulations, by exploiting the computing power of the 3DEXPERIENCE platform

Iterative refinement loop