

Il ruolo della proprietà intellettuale nell'evoluzione della giovane Start-up



Med-Tech start-up, spin-off of University of Sannio, Benevento ITALY

Our startup

Often Medical was founded in 2018 by a multidisciplinary research team from:

Optoelectronics and Photonics Group at the Department of Engineering of the University of Sannio in Benevento
(decades of experience in developing advanced fiber optic sensors for industrial applications)

Department of Medical Surgical Sciences and Medicine Translation of the University of Rome Sapienza
(experts in algology and invasive and mini-invasive techniques in pain therapy)

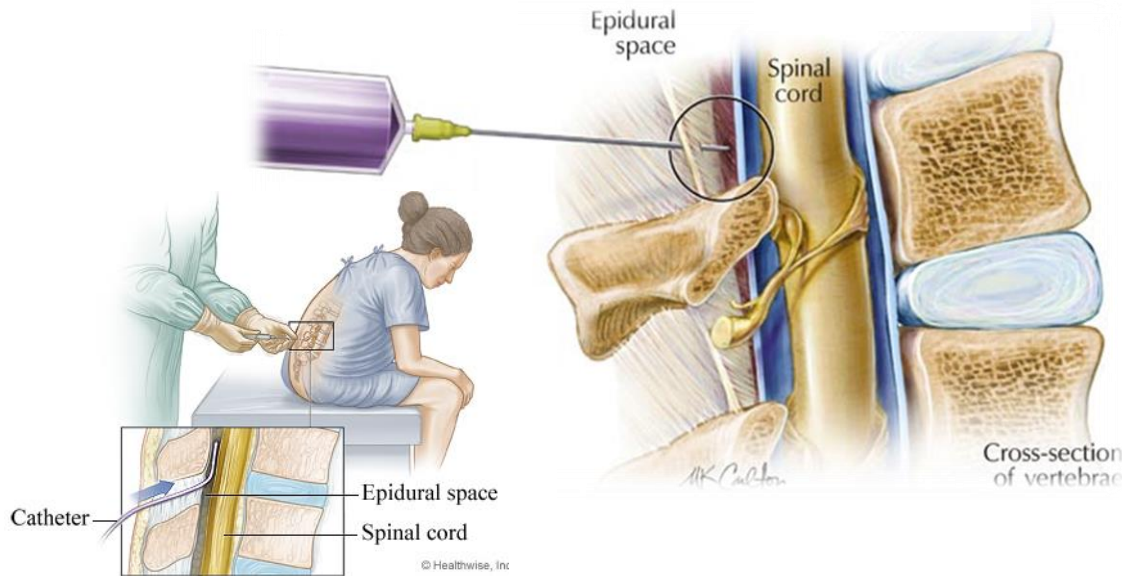
in collaboration with **DayOne**, incubator of high tech start-ups from European research centers



The mission: reshaping the future of Epidural Anesthesia

The epidural Anesthesia

The most commonly performed procedure for pain relief



Loss of resistance (LOR) technique



1. A needle is manually inserted into the epidural space (ES). On entering the ES, an abrupt drop of resistance on the plunger is perceived.

'blind' technique



2. A catheter is inserted into the patient's back through the needle and left in position. The drug is administered through the catheter

The clinical need

*Doctors still use **manual approaches** for performing epidurals*

The success depends on the operator experience

Failure rates up to 30% in clinical practice

British Journal of Anaesthesia 109, (2) 144-54 (2012)

In Italy, Extra cost of about 300M/year for the National Health Service

The market

It is estimated that each year about 3% of people undergoes an epidural

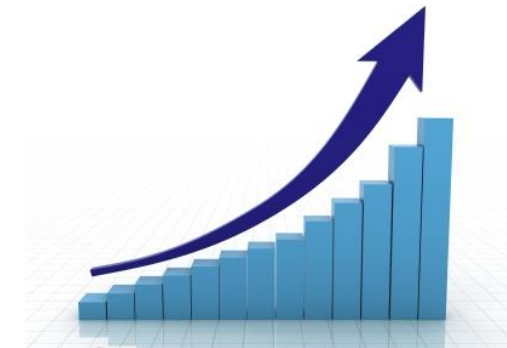
Number of people receiving epidurals annually

	A= # people	B= # epid/yr	B/A
USA	319 M	11 M	3.4%
ITALY	60 M	1.6 M	2.6%
EUROPE	740 M	22.2 M	3%

quote from the New England Journal of Medicine in July 2014



- Other Purposes
- Labors and delivery



Epidural Market is continuously growing

GLOBAL EPIDURAL ANESTHESIA SYSTEMS MARKET, BY PRODUCT TYPE 2017- 2028 (USD MILLION)

Product	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	CAGR %
Catheters	351.4	391.1	429.1	470.0	514.1	561.3	612.0	665.1	721.8	782.3	846.5	914.7	8.68%
Needles	395.1	441.0	485.4	533.4	585.2	641.0	701.0	764.4	832.1	904.6	982.0	1,064.5	9.02%
Accessories	206.6	230.9	254.5	279.9	307.4	337.1	369.0	402.8	438.9	477.6	519.0	563.1	9.13%
Total	953.1	1,063.0	1,169.0	1,283.4	1,406.7	1,539.4	1,682.0	1,832.3	1,992.9	2,164.5	2,347.5	2,542.3	8.92%

Source: Trade Associations, Annual Reports, Government & Regulatory Bodies, Paid Databases.

Competitors

Passive devices

Episure®



<http://www.indigo-orb.com/products/episure-epidural-LOR-syringe.php>

Epidrum®



<http://www.exmoorinnovations.co.uk/index.php/epidrum/epidrum-what-is-it>

Tuoren LOR®



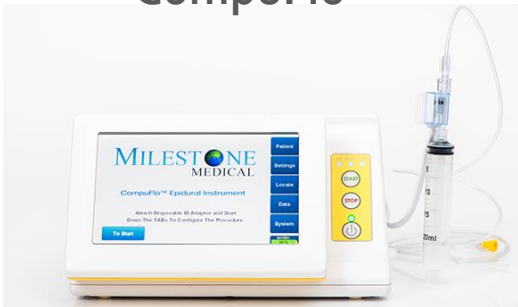
<http://www.tuoren.com/en/index.php?s=/product/show/id/1499.html>

- Simple
- Visual feedback
- High compatibility with standard kits and procedures

No catheter placement monitoring!

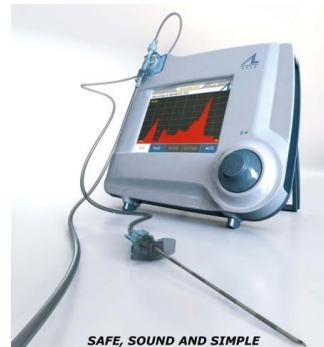
Active devices

CompuFlo®



<https://www.milestonescientific.com/products/compuFlo-epidural>

APAD®



<http://www.qrsinternational.nl/medical-devices/apad-acoustic-puncture-assist-device/>

EPI Detection®



<http://saeummeditec.com/>

- Visual/acoustic feedback
- Injection record database (except Epidetection)
- Compatibility with standard kits and procedures

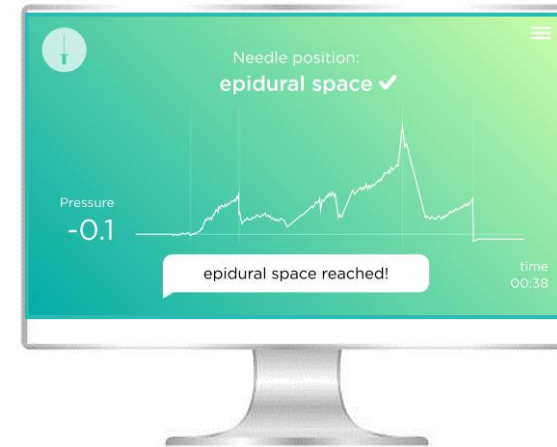
Our solution

We developed an innovative system based on a proprietary *optical fiber sensor technology*

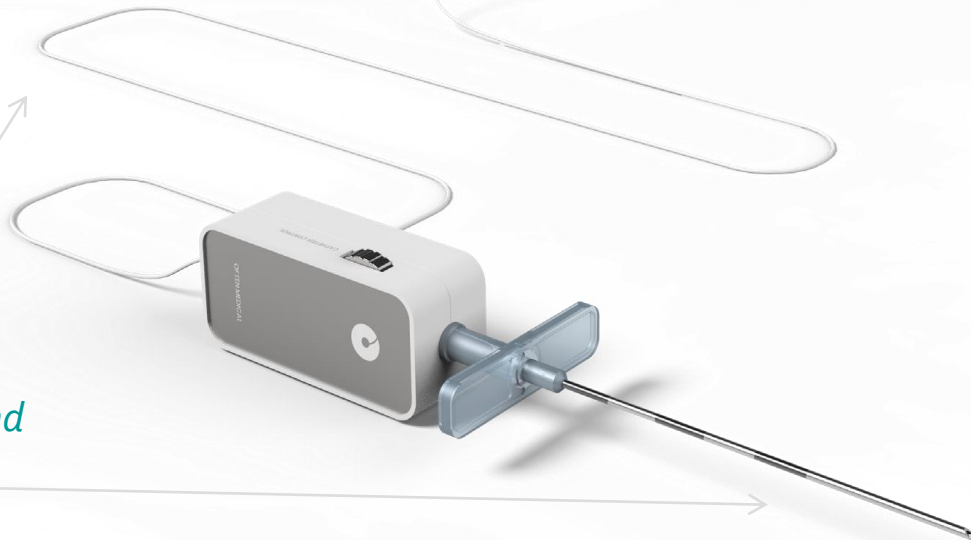
Interrogation unit



Display unit

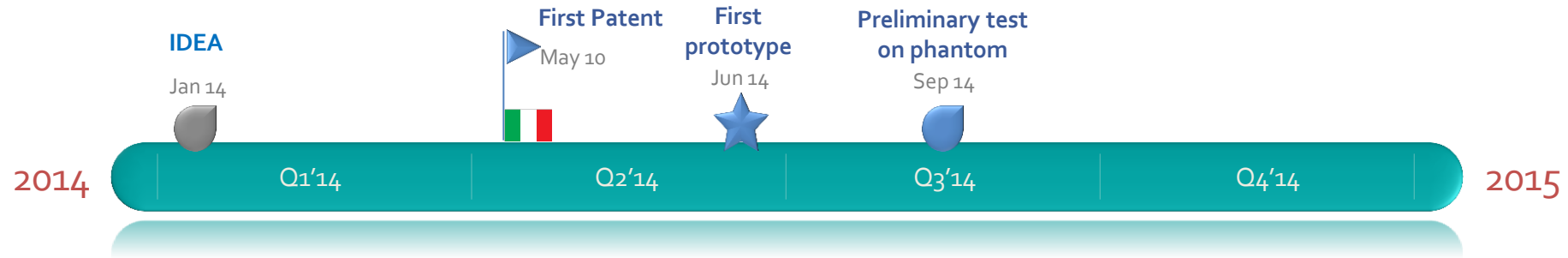


Sensorized catheter and needle



Our smart needle measures in real time the pressure during the insertion making the whole procedure objective and less operator-dependent

Our story



- **Idea:** The project is aimed to meet a clear *clinical need raised by anesthesiologists*
- **First patent:** we recognize that the idea is new and compatible with an industrial device able to have a strong impact in the specific medical sector with an *interesting market*-> this pushed us to write a patent (deposited in Italy, one year priority worldwide) but...:
- **Critical issue:** the patent is written with a strong focus on the concept more than on the technical aspects that are still undefined
- **First prototype:** a preliminary mock-up is fabricated and first test are carried out on an epidural phantom tissue used for training purposes.

Our story



- **First tests on animal (in-vivo)** : our prototype is tested on animals (study authorized by Italian Ministry of Health) Phantom and Animals studies help us to recognize that the original idea and prototype need a significant review
- **Second Patent**: we give up with the first patent and prepare, **in collaboration with leading European intellectual property firm** a new draft of the patent including all the technical specifications collected during tests performed on both phantom tissue and animals.
- **The second patent focuses on the device instead of the concept** and it is much more detailed than the first one
- Based on our experience, the technical details are the real value of the intellectual property

Our story



- **The second prototype** is developed according to all the inputs received by anesthesiologists (our partners and opinion leaders) who used our device. Phantom tests confirm our performance expectations and the advances in respect to the first prototype.
- **International Patent**: the second patent works so that we decided to go for a **PCT**

Our story



- Our team meets a **startup incubator (Day One srl)** during the event «User-driven innovation: a new way to develop technologies and startups together with large companies» organized by Unisannio;
- *The presence of the patent is of fundamental importance to win the selection process.*
- Thanks to the collaboration with the incubator we prepared a **business plan** and started to look around for fundings.
- We apply to the call **“Bando supporto allo sviluppo di spin-off e startup innovative”** - POR Campania FESR 2014-2020 (project value 500k, co-financing 35%)
- *The availability of an (international) patent gives scores and positive comments during the process evaluation.*

Proof of Concept Animal Study

Fully functional prototype



Successfully tested on

1. Epidural phantom tissue

2. In-vivo test on pigs

64 procedures
100% of accuracy



Publications on scientific journals

Best Poster Award

Chemical, Environmental,
Biological and Medical Sensors



IEEE JOURNAL OF SELECTED TOPICS IN QUANTUM ELECTRONICS, VOL. 23, NO. 2, MARCH/APRIL 2017

Optical Guidance Systems for Epidural Space Identification

Benito Carotenuto, Alberto Micco, Armando Ricciardi, Ezio Amorizzo, Marco Mercieri,
Antonello Cutolo, and Andrea Cusano

(Invited Paper)

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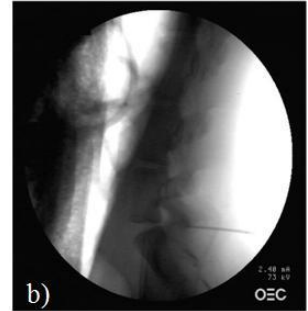
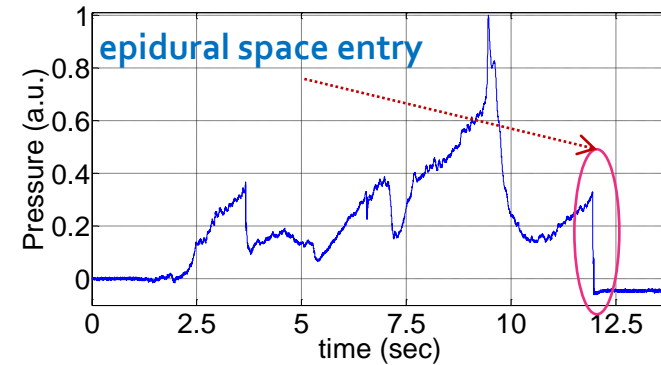
Optical fiber technology enables smart needles for epidurals: an *in-vivo* swine study

BENITO CAROTENUTO,¹ ARMANDO RICCIARDI,^{1,3} ALBERTO MICCO,¹ EZIO AMORIZZO,² MARCO MERCIERI,² ANTONELLO CUTOLO,¹ AND ANDREA CUSANO^{1,4}

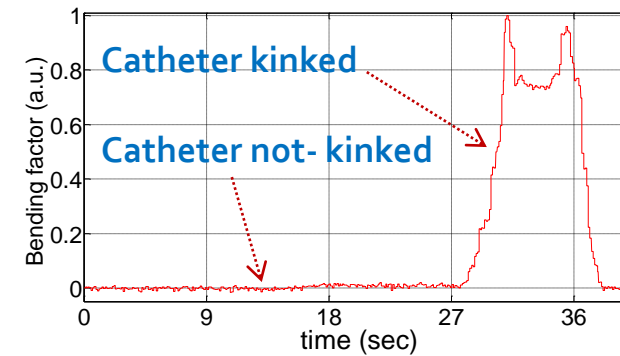
In-vivo tests on animals

authorized by Italian Ministry of Health (auth. N. 554/2017)

1. Needle
placement



2. Catheter
placement

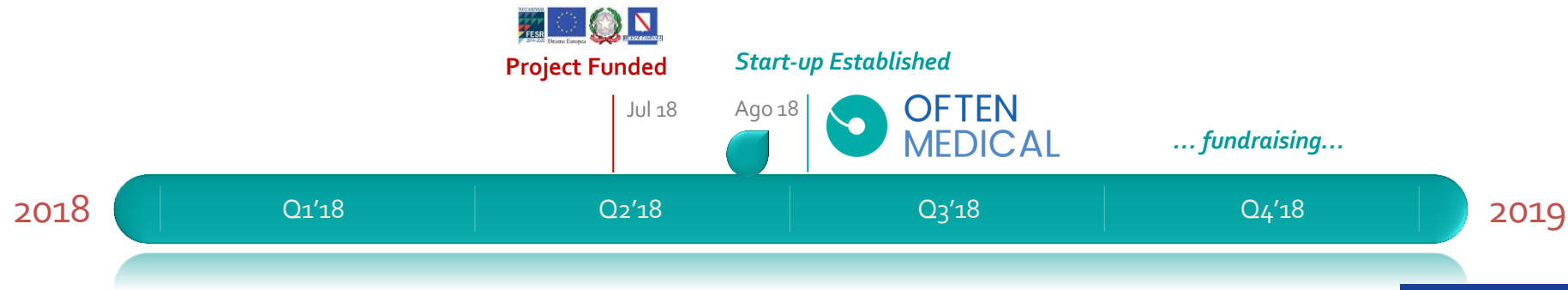


Article

Smart Optical Catheters for Epidurals

Benito Carotenuto¹, Armando Ricciardi^{1,*}, Alberto Micco¹, Ezio Amorizzo²,
Marco Mercieri², Antonello Cutolo¹ and Andrea Cusano^{1,*}

Our story



- The **project is funded** and finally **the startup is established**.
- New projects are submitted to the **ERC (European Research Council)** -> we obtain the **'*seal of excellence*'** certificate that will give us the possibility to win new public grants...
- ***Again, the availability of an (international) patent gives scores and positive comments during the process evaluation.***
- We start to meet **Venture Capital (VC) firms** at both national and international level



Our story



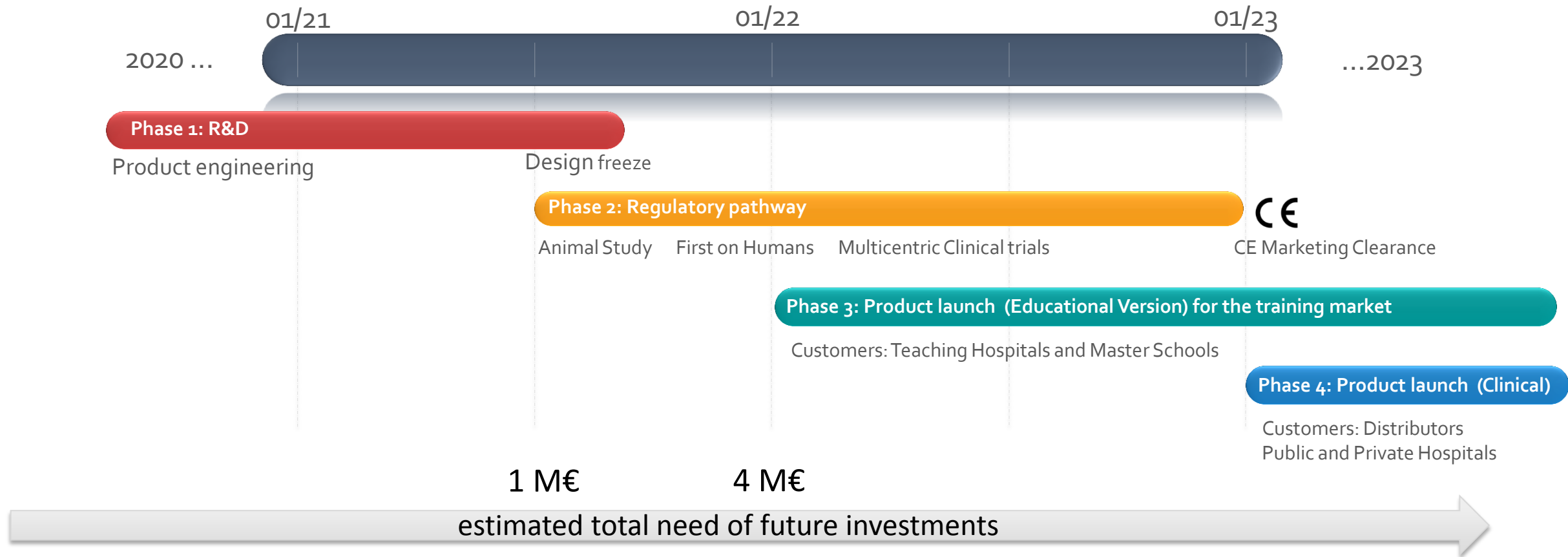
Often Medical is financed by **the Vertis Venture 3 Tech Transfer**, a venture Capital fund managed by Vertis SGR and Venture Factory (seed fund 575k).

During negotiations, the investors considered the presence of an international patent a conditio sine qua non for the equity injection. Often Medical has the exclusive license of the patent.

In the mean time the patent is granted in Europe (20 countries), United States, Canada and China.

Patent costs incurred to date are about 100Keuro / Patent manteinance expenses are about 20k/per year

Our future Go to market



Recently, Often Medical was the first among the startups that can be financed within the call “Campania Start Up 2020” - PO FESR 2014-2020 (project value 420k, co-financing 30%) **Again, the availability of an (international) patent provides higher score and positive comments during the process evaluation.**

Awards and Endorsement



Runner-up in the life science category in 2019



Finalist at Premio Gaetano Marzotto 2019



Funded by a VC 2019



Grant winner «Campania startup» 2017 and 2020 editions



The European House
Ambrosetti

Selected for the call 'Campania Tech Revolution 2020'

Our project has been endorsed by

Dr. Ezio Amorizzo



Dr. Marco Mercieri



Dr. Enrico Barbara



Dr. Andrea Tognù



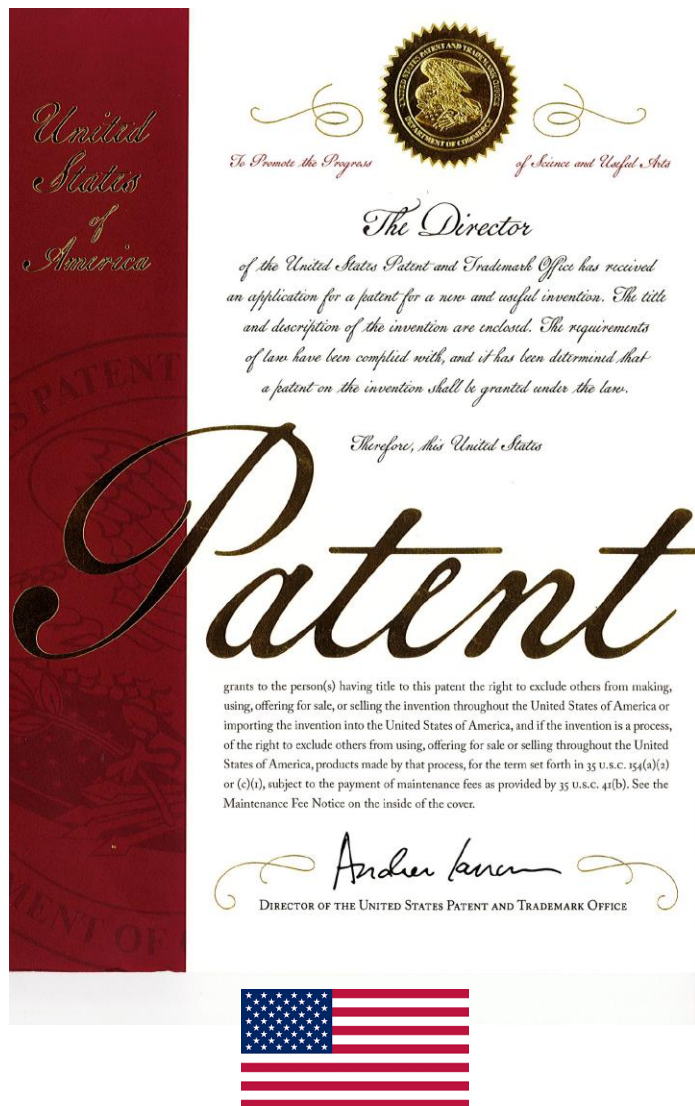
President and Incoming President of



European Society
of Regional Anaesthesia
& Pain Therapy
ESRA - ITALIA

and many others...

The certificates



Thank you for your kind attention



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申请人或专利权人: 埃齐奥·阿莫里佐 安德里亚·库萨诺 安东内洛·库托洛 马尔科·梅尔切里 阿尔贝托·米科 阿尔曼多·里恰尔迪

发明创造名称: 用于医用针插入的引导系统

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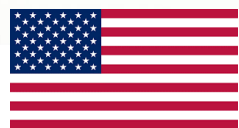
按照财税[2019]13 号及京财税[2019]196 号通知, 增值税小规模纳税人减按 2.5 元缴纳印花税。

审查员: 自动审查

审查部门: 专利局初审及流程管理部

联系电话: 010-62084704

200802 2019.9 纸质申请, 回函请寄: 100088 北京市海淀区衙门楼西土城路 6 号 国家知识产权局专利局受理处
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