

## French MedTech BodyCAP launches its “eCelsius Medical System”, a connected ingestible thermometer for medical applications in the United States.

**BodyCAP, a French MedTech company, has taken another step forward with the approval of its “eCelsius Medical System” connected medical device by the US Food and Drug Administration (FDA). This thermometer, integrated into a capsule that is simply swallowed, enables a continuous and accurate measurement of core body temperature throughout the gastrointestinal transit until it is expelled. Already widely adopted in the sports and military sectors, the eCelsius Medical System connected medical device will now be available in the United States for medical use to measure core body temperature in patients for diagnostic or therapeutic purposes (clinical research, infectiology, oncology, internal medicine).**

As a marker of infection, hyper- or hypothermia, body temperature is an essential indicator in diagnosing a patient’s state of health, and continuous, accurate measurement of this parameter is vital in the monitoring of patients in critical situations. However, until now, only a few restrictive devices, such a rectal or oesophageal probes, have been able to combine an accurate and continuous monitoring of core temperature. To meet this need, French MedTech BodyCAP, based in Caen (Calvados), has developed the eCelsius Medical System, a Class II medical device that enables this measurement to be carried out in real time using a small miniaturised electronic capsule, which is less than 2cm long, that can be swallowed (see photo opposite).



This condensed technology communicated in real time at a frequency of 30 seconds with a dedicated monitor, the eViewer Medical, which records the data autonomously and triggers alerts if the threshold is exceeded. The temperature is accurate to within  $\pm 0.1^{\circ}\text{C}$  of the human physiological range between  $36\text{-}41^{\circ}\text{C}$ , and the communication protocol guarantees data security.

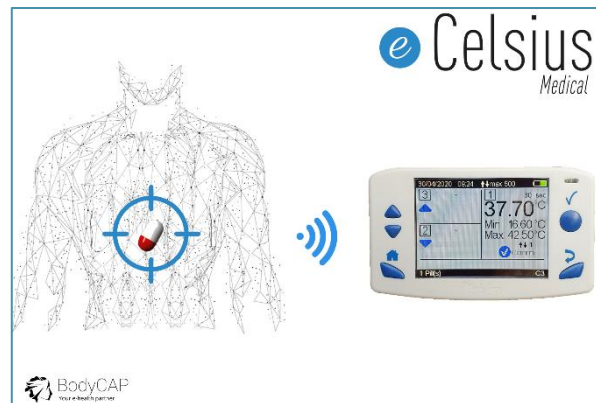
### **Precise, continuous, non-invasive body temperature monitoring**

This medical device can be used in both research and clinical applications. The major areas currently targeted are:

- **Infectiology:** Detection of the onset of an infection through a rise in temperature. The “eCelsius Medical System” secures patient monitoring.
- **Oncology:** Early detection of fever peaks in patients undergoing chemotherapy, reducing the time taken by medical staff to intervene.

## Expertise in assembling the device and optimising communication

Designed in-house by the BodyCAP teams, the electronics are encapsulated in a biocompatible material and sealed in a medical-grade PVC capsule. The capsule is eliminated naturally by the patient, guaranteeing an operational life corresponding to the individual characteristics of gastrointestinal motility (on average 2 +/- 1.5 days and up to 6 days). Every aspect of this technology has been studied and tested to ensure optimum performance and eliminate any risk of blockage or intoxication.



The result of a fusion between research into human physiology and microelectronics, this connected capsule has been used since 2016 in military and sports applications, for detailed analysis of hypothermia episodes during marathons and the Olympic Games etc. 90,000 capsules have been used over the last 5 years. The company produces all its capsules in France and generates 90% of its sales internationally.

Available from January 2024 for medical use, the amount of sales should rapidly reach several tens of thousands of units per year.

The next regulatory step in the United States is to obtain FDA approval for the entire device, including the data transmission chain to the cloud. Cybersecurity is one of BodyCAP's priorities, and this security requirement is fully integrated into the development of the device.

*"The approval of our device for medical use is a major step in the company's growth. It is the culmination of our investment in R&D and our expertise in monitoring physiological parameters more accurately in vivo, in real time. For patients, the use of this device makes treatment more effective in several types of pathology, and we will continue to provide new solutions to optimise care and prevent complications",* concludes Sébastien MOUSSAY, co-founder and Chairman and BodyCAP.

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### About BodyCAP

BodyCAP is a company that designs, develops, and markets wireless and miniaturised physiological measurement solutions. Founded in 2011, BodyCAP has developed expertise in ultra-miniaturised systems, embedded software and wireless communication. In particular, BodyCAP markets eCelsius Performance, a communicating electronic capsule dedicated to gastrointestinal core temperature measurement. BodyCAP operates in the sports, military, professional, clinical, and medical sectors. <https://www.bodycap-medical.com>



### Press Contacts

Agence PRPA

Valentine Martin – [valentine.martin@prpa.fr](mailto:valentine.martin@prpa.fr) – 06 32 29 43 82

BodyCAP

+33 (0) 2 61 53 03 29

[contact@bodycap.io](mailto:contact@bodycap.io)