

PRESS RELEASE

Devicare announces the positive results of the clinical trial with Lit-Control[®] to prevent the encrustation of catheters in patients with lithiasis

- **This pioneering international study has been conducted with the participation of nine Spanish hospitals renowned in urology, led by Bellvitge in Barcelona**
- **Dr Carlos Torrecilla: “We have a solution that will help medical practice and make it safer to manage patients with a double J catheter implant. It will be a revolution”**

Barcelona, 13rd December 2018 – [Devicare](#) and nine leading Spanish hospitals in urology have successfully completed the [clinical trial](#) which demonstrates the efficacy of the combined use of a [medical device](#) (Lit-Control[®] pH Meter) and a [nutraceutical](#) (Lit-Control[®] pH Down) to prevent the encrustation of double J catheters by **monitoring urinary pH and supplying phytates (crystallisation inhibitors)**.

The results of this pioneering study at the international level will be presented in the [Meeting of the Groups of Lithiasis, Endourology, Laparoscopy and Robotics Meeting](#) of the Spanish Association of Urology in January in Palma de Mallorca and in the [European Association of Urology Congress](#) in March in Barcelona in front of more than 10,000 urologists. The solution provides a response to an **unresolved medical need** which affects an important part of the **patients affected by urolithiasis**.

“These clinically significant results show that we have a solution that will help medical practice and make it easier to manage patients with a double J catheter implant. It will be a true revolution” explained **Dr Carlos Torrecilla**, the principal investigator of the trial, director of the Lithiasis Unit of the [Bellvitge University Hospital](#) and coordinator of the Lithiasis and Endourology Group of the [Spanish Association of Urology](#) (AEU).

A total of 105 patients participated in the **multicentre, randomised, double-blind, placebo-controlled trial** conducted this year in Bellvitge, the [La Paz University Hospital](#) in Madrid, the [Río Hortega University Hospital](#) in Valladolid, the [Puigvert Foundation](#), the [San Cecilio University Hospital](#) in Granada, the [Valme University Hospital](#) in Seville, the [Álvaro Cunqueiro Hospital](#) in Vigo, the [La Fe University Hospital](#) in Valencia and the [Santiago de Compostela University Hospital](#), with the participation of the Lithiasis Laboratory of the University of the Balearic Islands.

Finding solutions for other urological diseases

The innovative focus of Lit-Control® has generated great interest from the medical-scientific community both in how the study was conducted as well as its results. In addition to proving the product's clinical efficiency, doctors have gained greater insight into the encrustation process, thanks in part to the important role of **Dr Fèlix Grases and Dr Antonia Cost** of the [Lithiasis Laboratory of the University of the Balearic Islands](#).

In the words of Dr Jordi Cuñé from the Devicare scientific team, this trial is considered “a resounding success as it validates the working hypothesis and reinforces our firm commitment to providing innovative solutions in the field of urology”. The scientific and technological basis that the trial has achieved “will allow us to delve into the field of catheters, as well as to approach other unmet needs such as preventing Catheter Associated Urinary Tract Infections” Cuñé added. These types of patients are extremely prevalent within the geriatric population with spinal cord damage or cognitive impairment and with lateral impacts such as **high antibiotic consumption and the associated antibiotic resistance**.

In recent years, Devicare has designed an ambitious **development programme for nutraceuticals and medical foods**: “we want to provide the most rigorous clinical evidence with the collaboration of the best urologists, as has been the case in the double J study” Jordi Cuñé noted.

What is the double J catheter?

The double J stent catheter is a tube-shaped device, with a small diameter, made of different materials such as silicone, which is implanted in patients to facilitate the passage of urine from the kidney to the bladder when the ureter is obstructed by a stone as well as to prevent this obstruction. Patients may have a catheter for a few days, weeks or months.

Additionally, its use is also widely spread in the medical management of benign or malignant chronic obstructions, transplants, malformations or in palliative referral. In these cases the catheter may be implanted for long periods of time, even their entire lifetime, and is very susceptible to infectious processes and encrustation.

In Spain alone, around 90,000 double J catheters are implanted each year, being encrustation one of the most common issues. Due to dietary changes, the increased global temperature and other unidentified factors, we are observing an **increase in the rate of kidney lithiasis**¹.

More information:

- **[Interview to Dr Carlos Torrecilla](#)**

¹ Sorokin I., Mamoulakis C., Miyazawa K., Rodgers A., Talati J., Lotan Y. (2017). [Epidemiology of stone disease across the world](#). World J Urol. doi: 10.1007/s00345-017-2008-6.

.....

About Bellvitge Hospital

The Bellvitge University Hospital (www.bellvitgehospital.cat) belongs to the Catalan Health Institute (ICS) and is one of the five major university hospitals in Catalonia. It registers some 35,000 annual discharges. Accredited as a third level center, it has the technology and professional experience to perform the most complex healthcare procedures. It has been nine times TOP 20 in the ranking of the best hospitals in Spain. The hospital is a state of the art research center and member of the Biomedical Research Institute of Bellvitge (IDIBELL),

About Devicare

Devicare (www.devicare.com) is a technologically-driven company dedicated to developing digital therapeutic solutions (DTx) to improve in-home management of chronic diseases, combining diagnostics (Dx), monitoring (Mx) and nutritional therapies (Nx). These innovative solutions, such as Lit-Control[®] (www.lit-control.es) in urology are created based on the concept of patient empowerment so that patients can actively participate in managing their own health. The company holds 49 patents, a clinical programme with six studies in progress, strategic partnerships with renowned institutions such as the Puigvert Foundation and the University of the Balearic Islands' Laboratory of Renal Lithiasis Research, and 25 international agreements with pharmaceutical companies in the field of urology. The company's headquarters is located in the UAB Research Park in Cerdanyola del Vallès (Barcelona).

For further information:

Devicare

Gemma Escarré (Communications Manager)

M. +34 667 76 15 24

gescarre@devicare.com

Hospital Bellvitge

Press Office

Tel. +34 93 260 74 55

premsa.bellvitge@bellvitgehospital.cat