

# DEBN

DRUG-ELUTING BIOPSY NEEDLE

**PRODUCT DESCRIPTION**

## I. PROBLEM

Transrectal ultrasound-guided prostate biopsy (TRUS-Bx) is a standard method for histological diagnosis of prostate cancer and one of the most commonly practiced urological procedures in the world [1]. It is estimated that only in the United States of America there are more than 1.000.000 TRUS-Bx performed every year [2,3]. Due to transrectal approach and multiple sampling TRUS-Bx is associated with up to 7% risk of infectious complications like urinary tract infections, prostatitis, epididymitis or even severe sepsis and septic shock [4]. Therefore, there is an essential need for periprocedural antimicrobial prophylaxis which is indicated in all patients undergoing TRUS-Bx with the best evidence among the urological procedures [5-7]. European Association of Urology and American Urology Association guidelines on TRUS-Bx antimicrobial prophylaxis stated that oral fluoroquinolones are the first line prophylactic agents [1,8]. However, in the past few years an increased resistance of rectal flora to fluoroquinolones associated with a rise in severe infectious complications has been reported [3,9]. The main pathogen responsible for this phenomenon is fluoroquinolone-resistant *Escherichia coli* (*E. coli*) which causes most postprocedural sepsis episodes [10]. Rapidly growing literature on this issue showed a large percentage (>20%) of those strains present in rectal flora of patients undergoing TRUS-Bx [2,11]. This means that significant proportion of patients do not receive effective antimicrobial prophylaxis prior prostate biopsy. The existing methods to reduce the rate of prostate biopsy related infections include transperineal prostate biopsy, different regimens of oral, intramuscular and intravenous antimicrobial prophylaxis or targeted antimicrobial prophylaxis which requires rectal swab sampling before TRUS-Bx [11,12]. All of these methods have some disadvantages that result in their limited use [11,12]. The transperineal prostate biopsy is a more complicated and painful procedure and requires a general anesthesia. Until now none of various empiric antibacterial prophylaxis regimens that have been proposed, did not become the standard over fluoroquinolones and the choice of proper one remains debatable. Even targeted antimicrobial prophylaxis which is a promising method still needs more research concerning its efficiency [11].

### References:

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## II. PRODUCT

DEBN is a patent pending (PCT/PL2016/000006) medical device which is a novel approach to the problem of TRUS-Bx related infectious complications. It consists of polymer coated biopsy needle and anesthesia needle that release the drugs directly to the prostate during the procedure. This solution may allow the co-administration of various antibiotics, thereby broaden their spectrum of activity and potentially reduce the number of infectious complications. Presented model of DEBN contains poly(vinyl alcohol), ciprofloxacin and amikacin.

## III. INNOVATION

Transrectal intraprostatic antibiotics injections have been studied until now only as method of treatment for prostatitis and chronic pelvic pain syndrome. In 2013 Issa et al. published the first focuses on the biopsy needle as a vector of TRUS-Bx related infections [1]. Authors described a simple and effective method to reduce the risk of infection after prostate biopsy with formalin disinfection of the biopsy needle after each prostate biopsy core. They found an association between the use of this technique and lower incidence rate of urinary infection and sepsis. However, repeat formalin exposure during prostate biopsy may increase the risk of toxicity and adverse effects [1,2]. DEBN is the first medical device which enable simultaneous organ-targeted delivery of antibiotics during prostate biopsy procedure. Novelty, inventive step and industrial applicability of DEBNs have been confirmed by a decision of European Patent Office.

References:

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#### IV. TECHNOLOGY READINESS LEVEL (TRL)

TRL 4 – DEBN prototype and technology was validated in laboratory (TRL 4: basic technological components are integrated to establish that they will work together). If you want to more in-depth information contact us at [contact@debn.eu](mailto:contact@debn.eu).

#### V. SAFETY

Intraprostatic injection was first described in 1983 by Baert et al. [1]. Since then, a number of investigators have advocated direct injection of antibiotics (including amikacin and ciprofloxacin) into the prostate gland due to prostatitis [2-6]. Those authors demonstrated safety and feasibility of this procedure. However this method has never been used as an antibiotic prophylaxis prior prostate biopsy.

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## VI. EFFECTIVENESS

The high-performance liquid chromatography analysis and the bacterial growth inhibition test showed that DEBNs released high concentrations of amikacin and ciprofloxacin and have strong bactericidal activity against *E. coli*.

The addition of intravenous amikacin to oral ciprofloxacin prophylaxis significantly reduces the incidence of septicemia after prostate biopsy [1-3]. However, administering intravenous amikacin is not easy nor cost-effective and often requires hospitalization [4]. Drug-Eluting Biopsy Needle could deliver combined antibiotic prophylaxis to the prostate without hospitalization need. Furthermore, Bahk et al. concluded that the direct intraprostatic injection of fluoroquinolone provides antibiotic activity in the entire prostate [5].

### References:

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