

Joke Donné¹, Koen Beyers^{1,2}, Judith Urlings^{4,5}, Alejandra Rios Cortes¹, Ronald Van den Bossche¹, Nette Meers¹, Quinten Van Avondt¹, Tine Provinciael¹, Laura Hochstenbach³, Paulette Wauben³, Claire Huijnen³, Bianca Ceccarelli^{4,5}, Katherine Nelissen⁴, Vanessa Vankerckhoven¹
1 Novosanis, Belgium | **2** Voxdale, Belgium | **3** EIZT, the Netherlands | **4** Happy Aging, Belgium | **5** Hasselt University, Belgium

BACKGROUND & AIM

The first-void/first-catch urine (first 20 ml of the urine flow) is being used for the detection of sexually transmitted infections (STIs), in particular for (1) *Chlamydia trachomatis*, (2) *Neisseria gonorrhoeae*, (3) *Mycoplasma genitalium* and (4) *Trichomonas vaginalis*. Novosanis' Colli-Pee® is an innovative device for standardized, volumetric and hygienic self-collection of first-void urine.

The aim of the study was to design a next generation of the Colli-Pee® device optimized in architecture and materials for postal mailing.

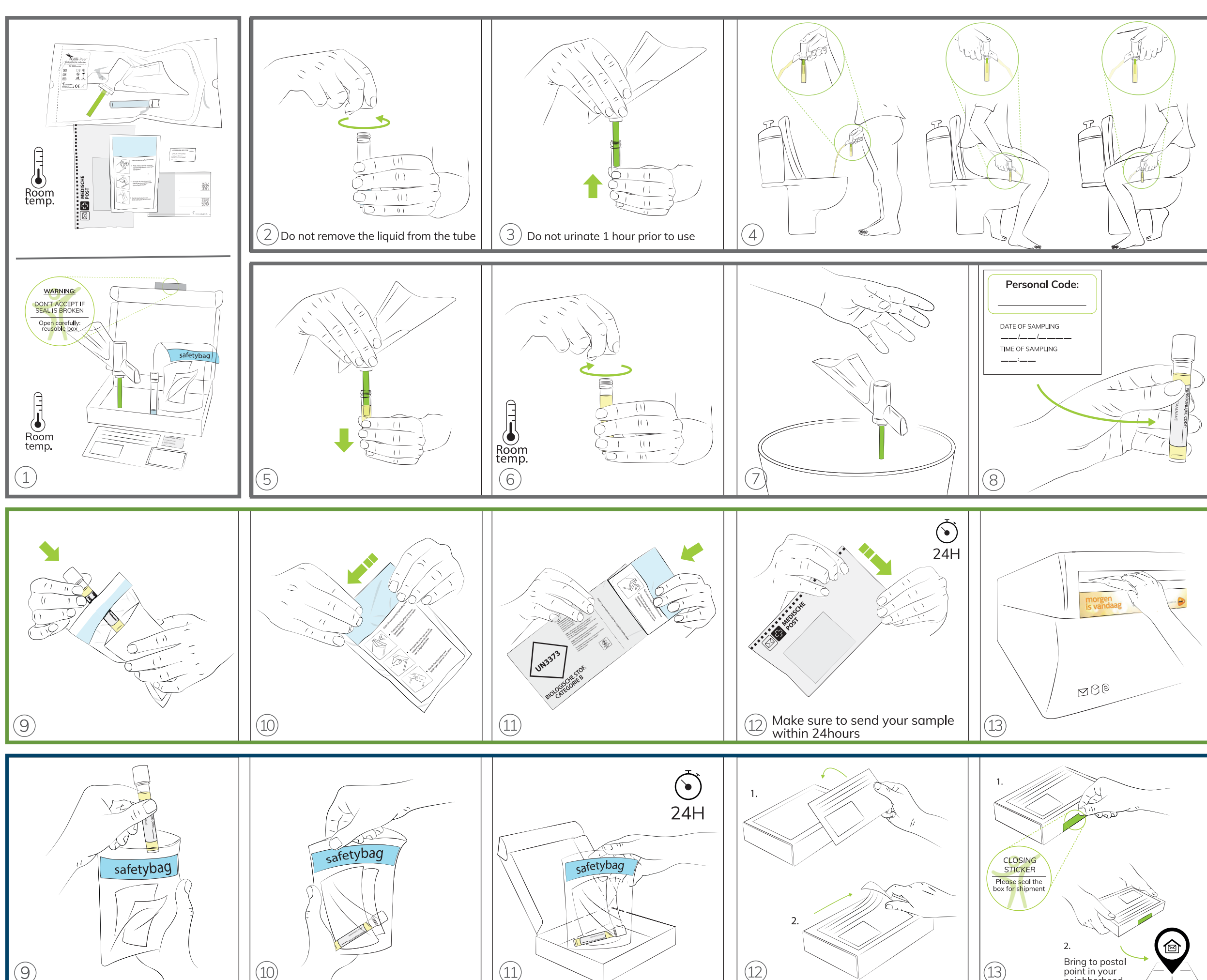
MATERIALS AND METHODS

The usability of the next generation Colli-Pee® was assessed for home-based use in 84 healthy volunteers; 50 in Belgium and 34 in the Netherlands. Volunteers provided feedback via an online questionnaire on the ease of use and the process of an online urine self-test: from requesting and receiving the Colli-Pee® urine collection system to the collection of urine to the returning of the sample by postal mail. The returned samples were checked for leakage and collected volume; as well as return conditions.



The final design of the Colli-Pee® for postal delivery and home-based collection contains a flexible and comfortable funnel and is combined with a standard 10ml tube (Sarstedt) to ensure compatibility with commercial carriers for sample processing.

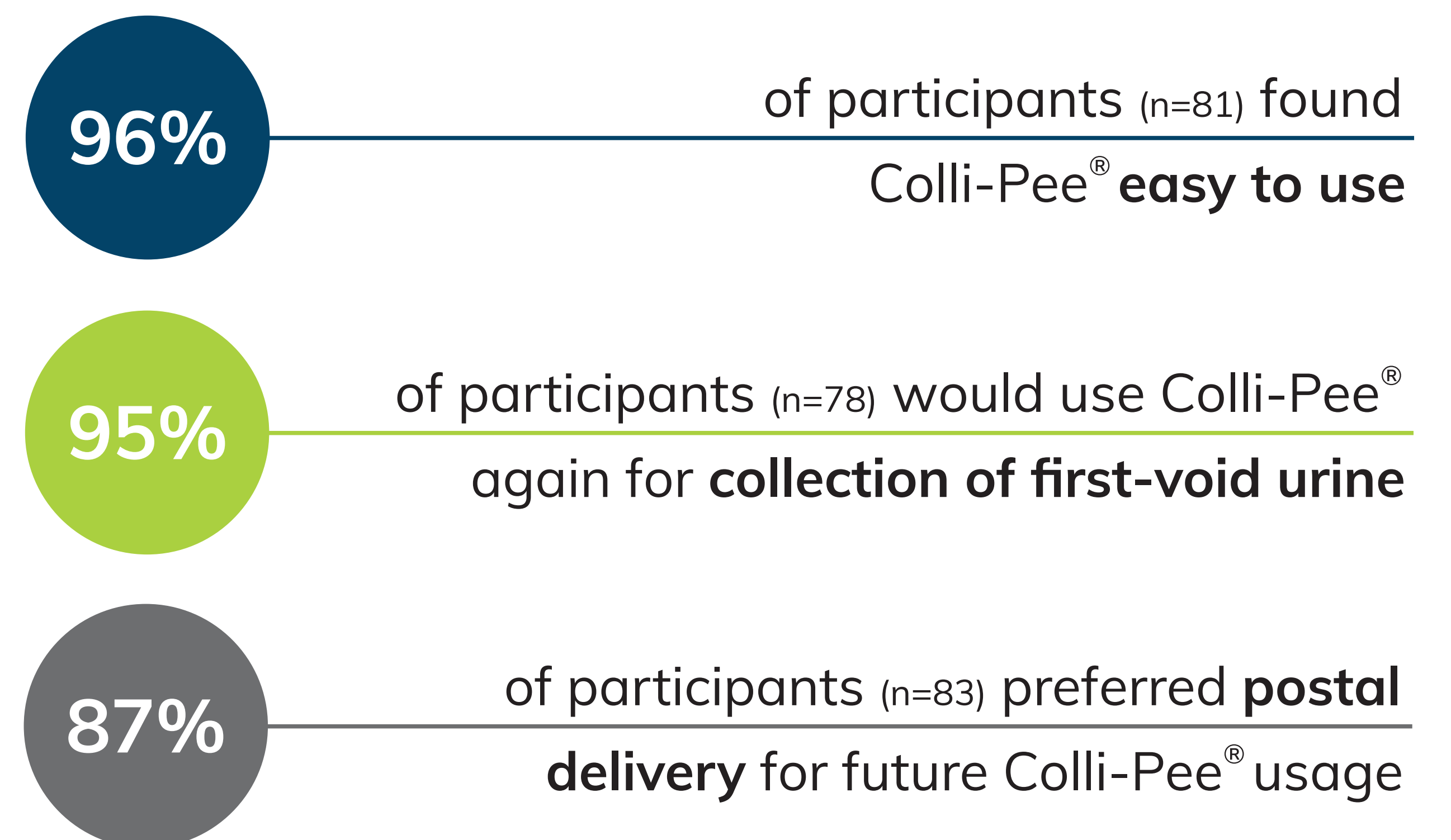
To be compliant to UN3373 (medical packaging) the package contains a regulated safety bag with absorbing tissues to allow for return shipment. Belgian regulations require the Colli-Pee® to be delivered in a postal box, while in the Netherlands an envelop is mandatory.



RESULTS

A total of 54 females and 30 males were included in the study, of which 24% were within the age range of 18-24 years, 39% of 25-34 years and 37% of 35-44 years old.

The volunteers completed the questionnaire on usability, consisting of yes-no, open and 10-point Likert scale questions. The most important findings comprise:



Participants had the impression that the **urine collection was performed correctly** (n=83)

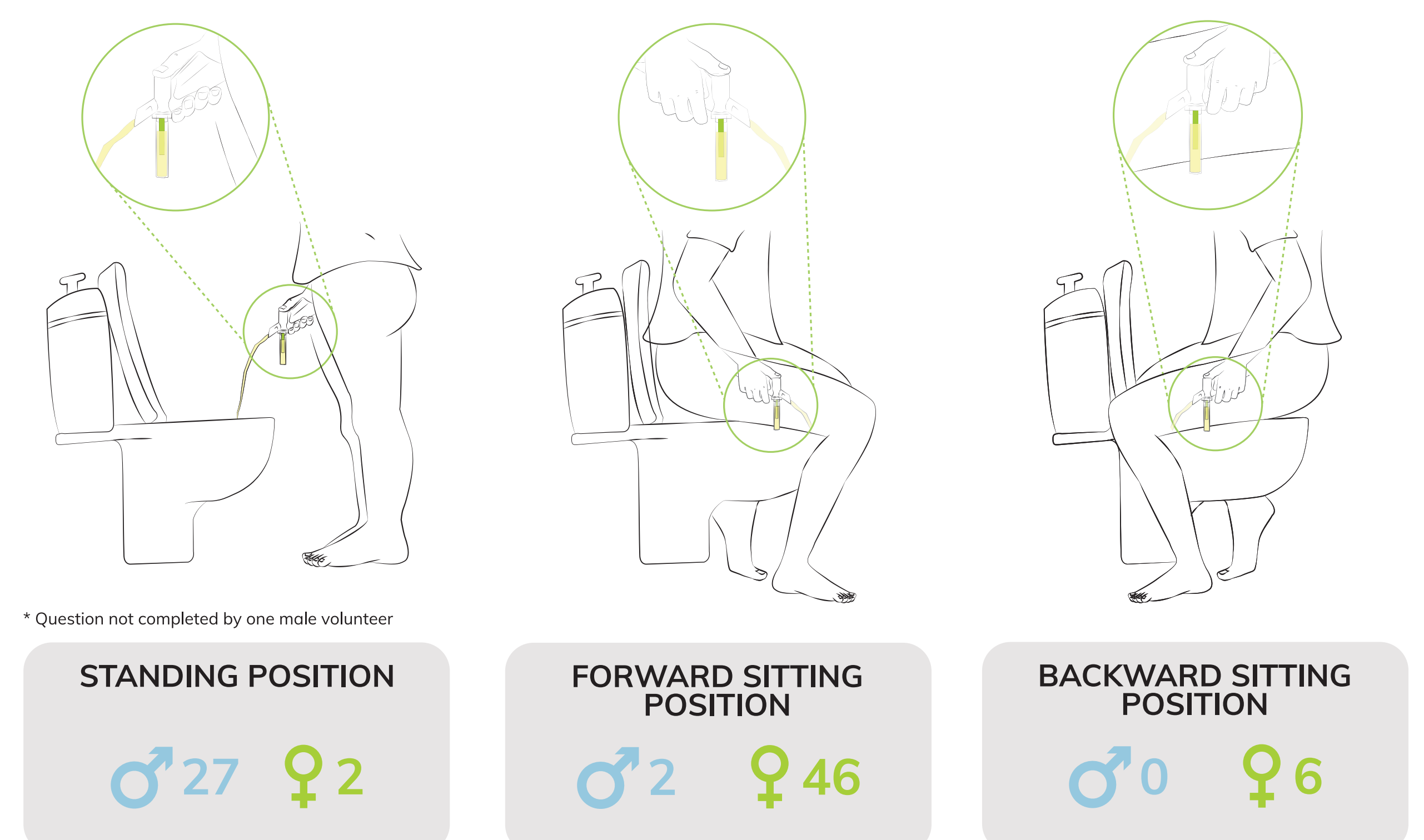


Participants found it a good urine collection method for a **home-based setting** (n=83)



10-point Likert scale: ■ ≤5 ■ 6 ■ 7 ■ 8

The Colli-Pee® can be used in three different pee positions, which were evaluated on usability. The results indicated that most men (93%) preferred the standing position, while a majority of women (85%) chose for the forward sitting position.



Furthermore, all returned boxes and envelopes with a urine sample were intact upon arrival.

CONCLUSION

The next-generation Colli-Pee® was well-accepted and offers a solution for home-based collection that is compliant with UN3373. The device allows for different pee positions, which was considered an advantage.