

Caya® Diaphragm Survey 2016

Results of the 3rd annual Caya post marketing survey

Methodology and recruitment. Women who purchased Caya Diaphragms in Germany between April and June 2016 were invited to participate in a consumer survey. Similar to previous Caya surveys, our aim was to collect “at least 100 responses”, so we closed the survey in July when a total of 103 women had completed the survey.

Women learned about the survey via an insert included in the consumer packaging. The insert provided instructions for how to access the questionnaire at the Caya Facebook page. For the first time, we used Caya FaceBook in German language to lead to this survey.

The first Caya diaphragm was sold in Germany on April 9th 2013 by the “Engel Pharmacy” to a woman in Fulda, Germany. Since then, more than 55,000 women in Europe, Canada, the US and Australia have purchased Caya as their contraceptive. As of 2016, women in more than 28 countries can purchase the Caya diaphragm. Product registrations and plans to supply Nigeria, Uganda, Morocco and Tunisia in 2017 are underway.

Results from the 3rd post marketing survey confirm that Caya fits women’s needs by providing a non-hormonal contraceptive option. More than 45% of the women from this survey reported they previously used method was a hormonal pill. In all, about 57% of the participants had previous experience with hormonal methods, such as hormonal pills, hormonal IUD, vaginal ring, contraceptive implant before they decided to use a Caya diaphragm. (see Figure 1)

Now that Caya® is in its third year of marketing in Germany, this survey suggests that more women who have never used a diaphragm before are choosing Caya. Only 1% of women in the 2016 survey reported previous diaphragm use compared to 18.2% in the 2014 survey reporting on the first year of consumer experience. It makes sense that as word spreads about Caya; more women who are looking for an alternative method may consider using this.

This result also is similar to responses where about 98% of women confirmed this was the first time they used the Caya diaphragm (see Figure 2).

Figure 1. Which contraceptive method did you use before?

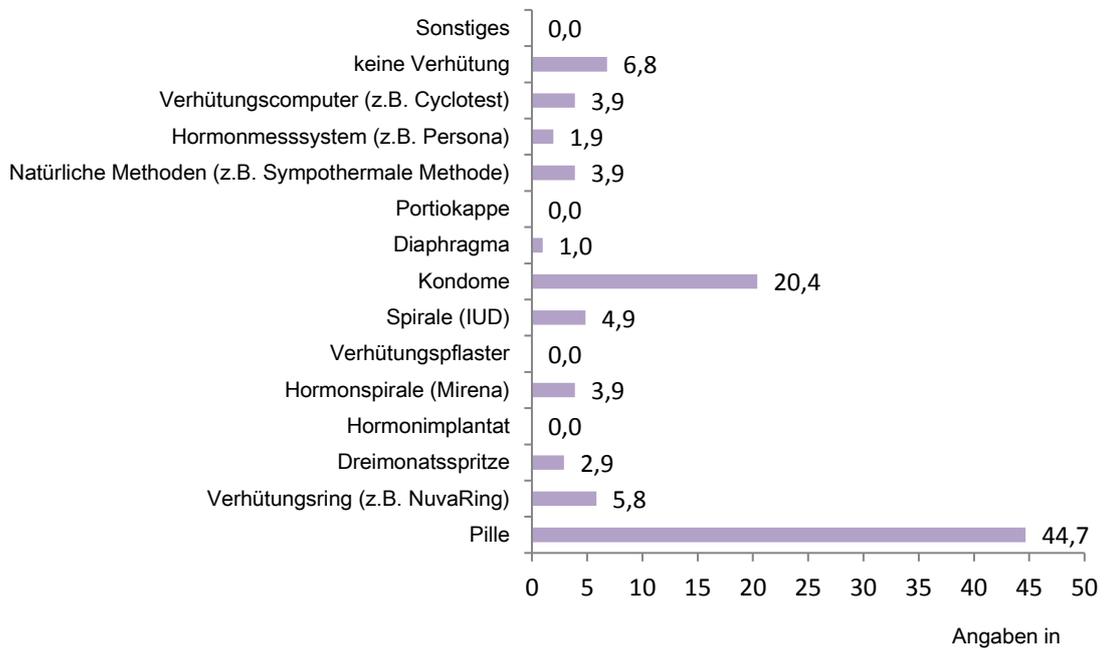
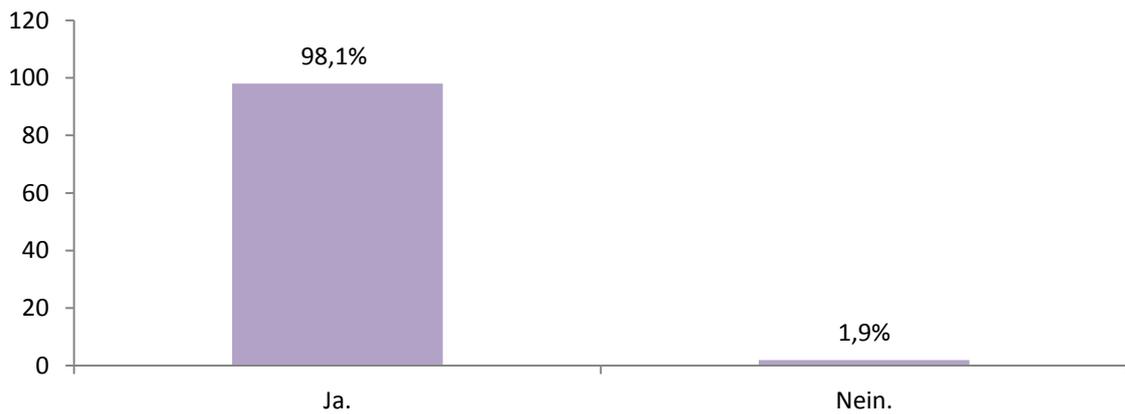
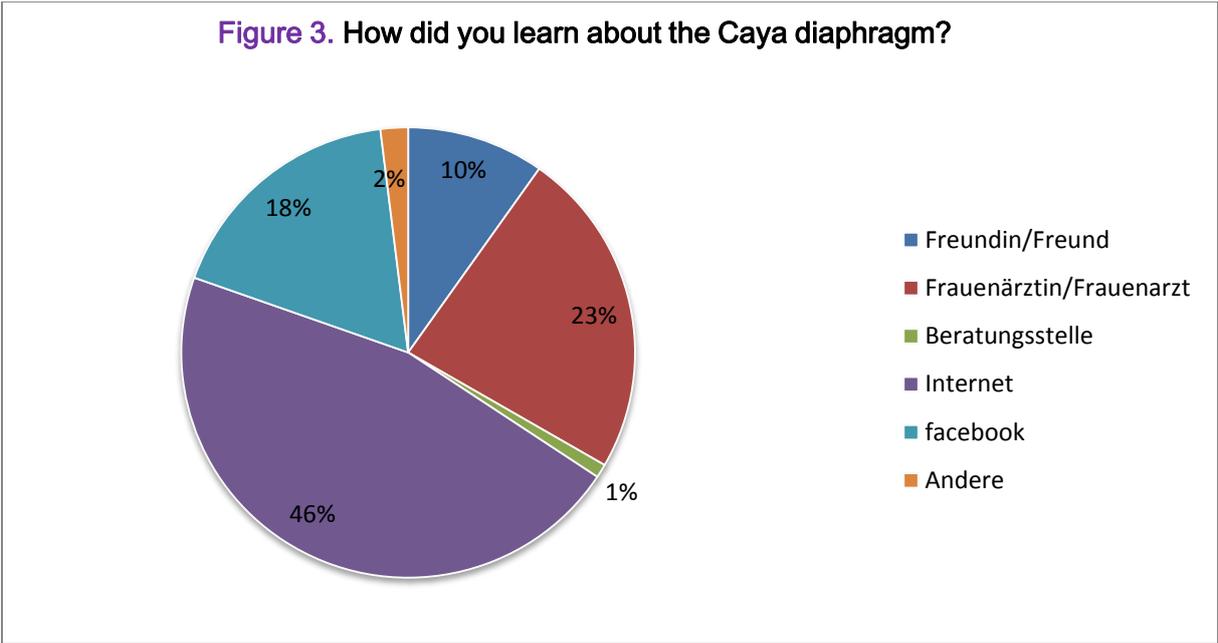


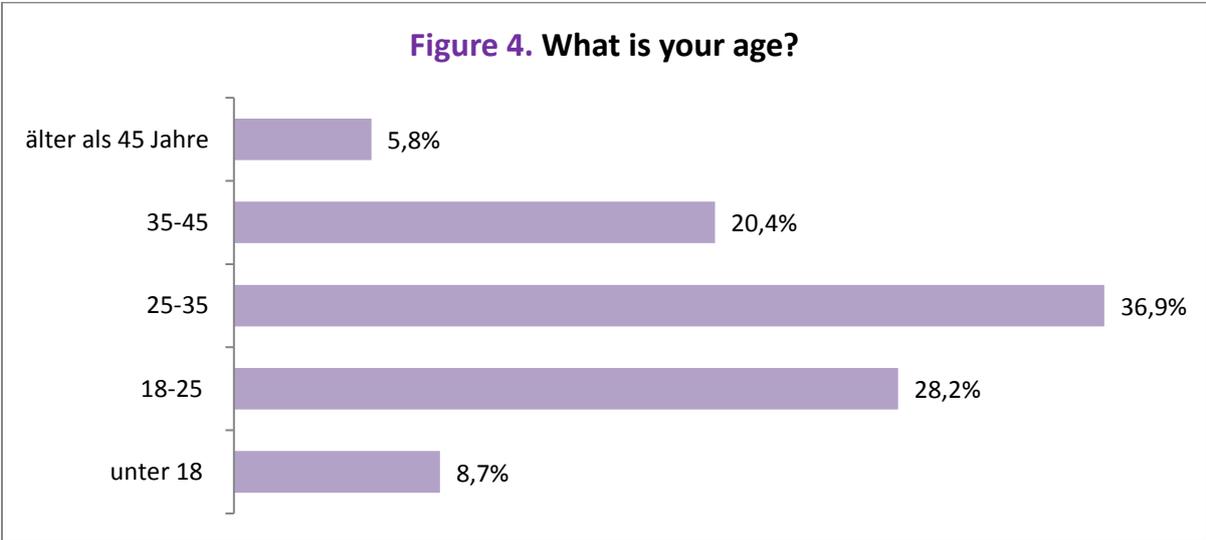
Figure 2. Is this the first time that you use a Caya diaphragm?



About 64% of the women reported they learned about Caya diaphragm via the internet and 18% of this group specifically reported they learned about Caya by Facebook, The German-language Facebook site was launched in March 2015 and contains informative posts about using Caya diaphragm. Healthcare providers, such as gynecologists, are the next most cited source of information about Caya, with 23% of the participants reporting they first heard about Caya diaphragm at their check-up visit at the gynecological practice. During the last survey (2015) about 15% of women said they learned about Caya from professionals. This trend underlines need to continue the systematic outreach to healthcare providers with basic information about the Caya Diaphragm.



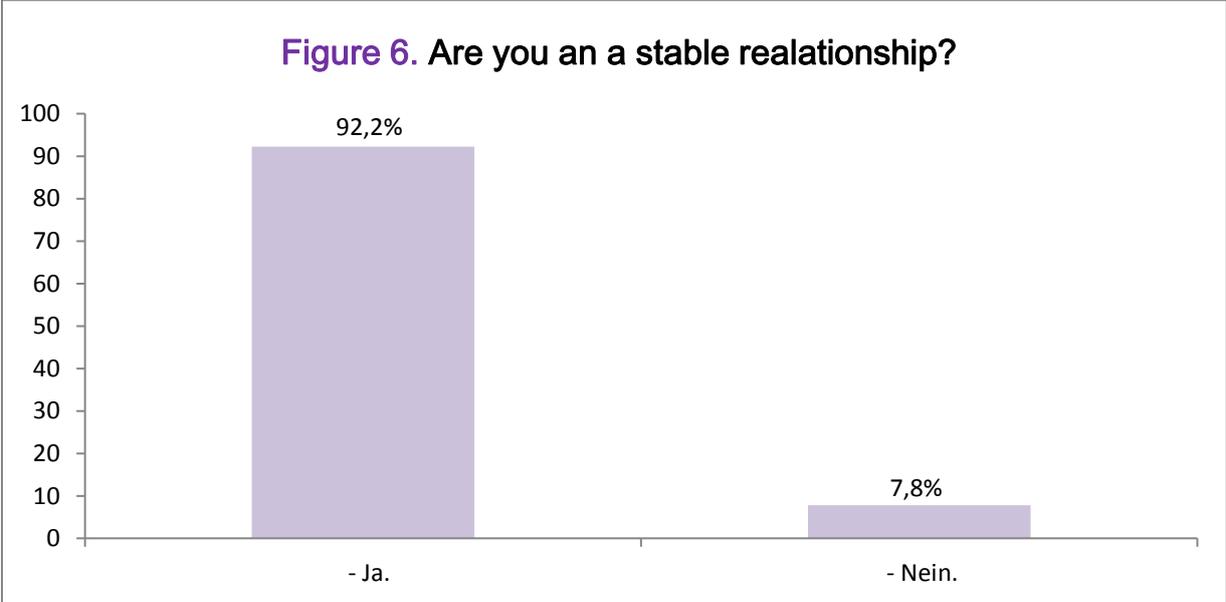
Similar to previous surveys, the 2016 survey shows that Caya diaphragm is being used by women of all ages. While most of the Caya using women are between 18 – 45 years, the percentage of women under 18 years increased from 0.7% in 2015 to 8.7% in 2016. This might be the influence of the activities via Facebook – but it show as well, that this young group of women are interested in alternatives to hormonal methods.



About 45% of the respondents reported not having children (similar to previous years) and about 92% report they live in a stable relationship. See Figure 5

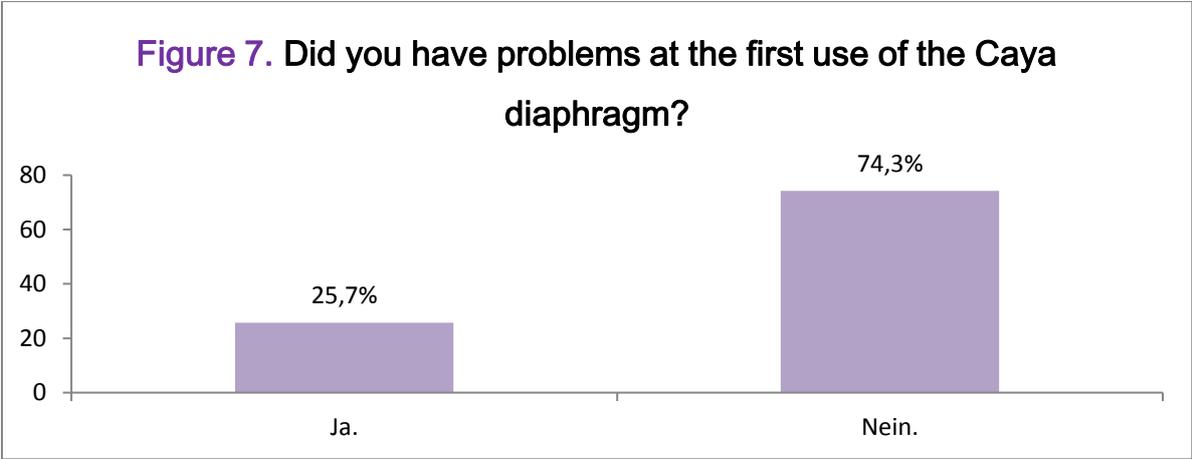


The percentage of women, who reported not living in a stable relationship dropped from 24.3% in 2015 to 7.8% this year. Without additional detail, it is difficult to understand the implications of this. While the Caya diaphragm is a contraceptive barrier method suitable for women at different stages in their life and relationships, there may be additional reasons why women who are not in stable relationship prefer other methods..

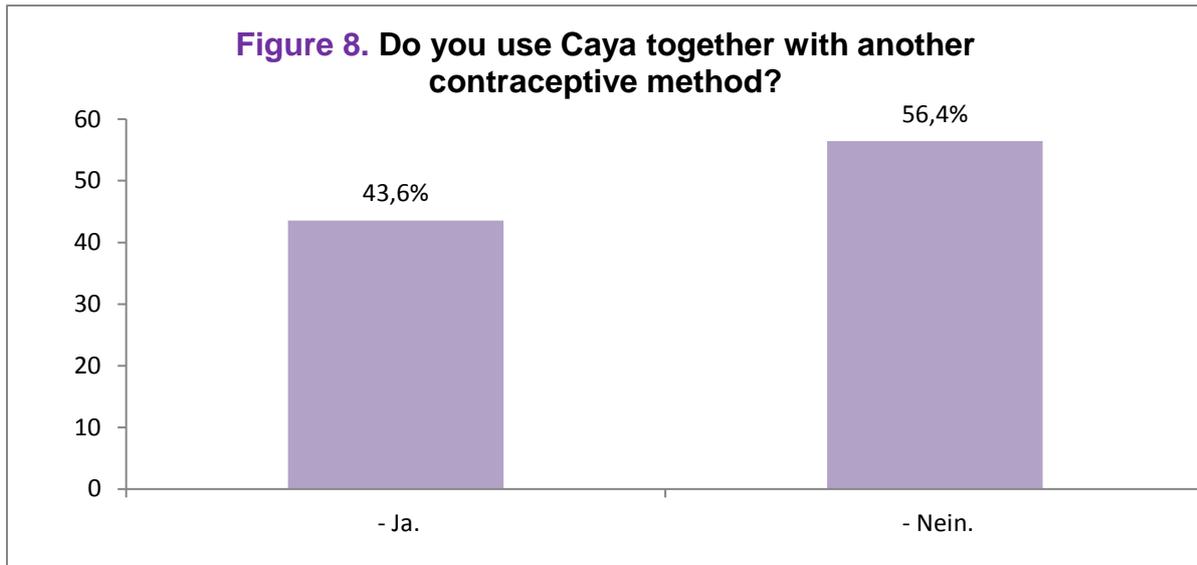


Caya seems to be easy to use. Most of the women in this survey were using this product and this method for the first time in their life. About 75% reported having no problems using Caya--even from the very beginning. This result underlines that the educational and instructional materials developed for the Caya diaphragm are appropriate for helping women understand “how to use” the Caya, and that the Caya is easy to use—even for new users. .

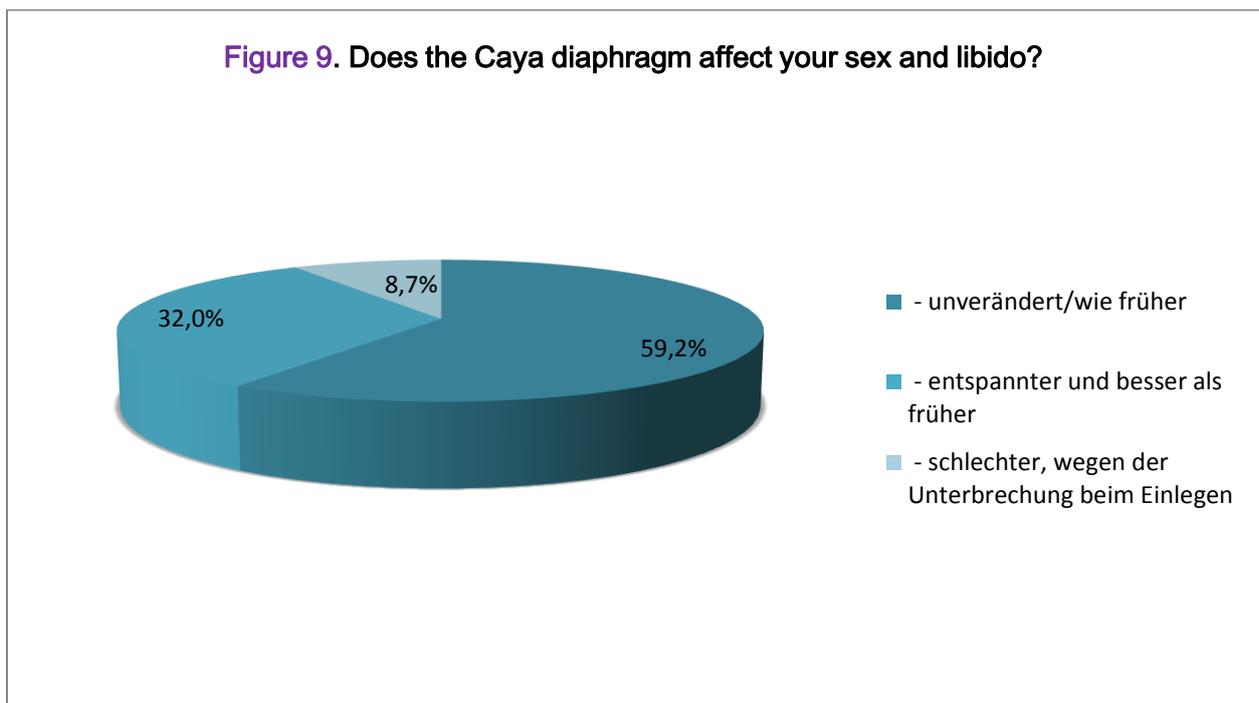
This “easy-to-learn for new users” experience also was documented during clinical studies implemented in the United States by the non-profit research organization CONRAD (www.conrad.org) who implemented the contraceptive effectiveness study when this device was known as the SILCS diaphragm. CONRAD reported that of the 500 participants in that study, nearly 80% correctly inserted and confirmed correct position of the diaphragm in the vagina after just reading the instructions (i.e. with no coaching or counseling from the provider)..



Some women (43.6%) reported using the Caya diaphragm in conjunction with other methods such as fertility awareness methods, “other natural methods”, or male condoms. More than half the respondents (56.4%) reported using the Caya diaphragm alone and no other method. Caya diaphragm is a safe and effective method by itself. In clinical studies, Caya diaphragm has similar effectiveness to traditional diaphragms that come in multiple sizes, and also to other barrier methods such as condoms. Consumers have various reasons for using a combination of methods. Some may use fertility awareness to understand when are their most fertile days so they can take extra caution during these times, others may want additional protection from STIs. Condoms are the recommended method for protection from STIs.

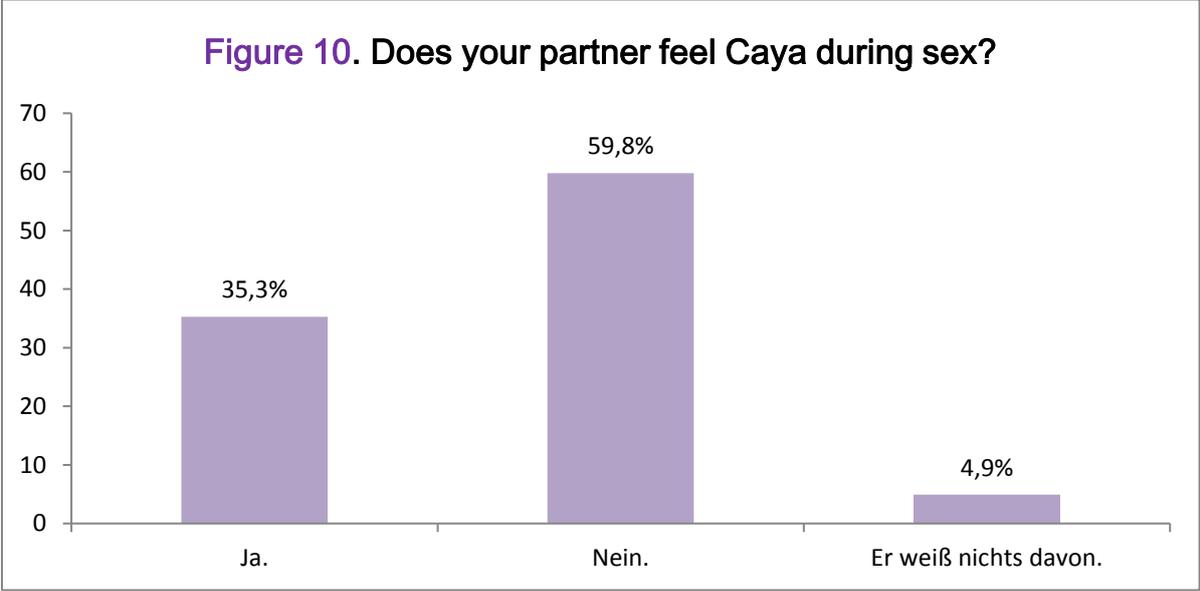


Similar to results from the 2015 survey, the answers about the impact of the Caya diaphragm on sex indicate that Caya does not interfere with sex for the female. About 32% of women confirmed that having sex with the Caya diaphragm is "better" than before and more relaxed!



For the first time, we asked in the survey 2016 whether the male partner "could feel the diaphragm while having sex" and if this was bothersome. About 60% of women reported their male partners did not feel at all the Caya diaphragm or did not feel it as "disturbing". 4.9% of male partners had not been informed their partner was using the Caya diaphragm. The interpretation of answers of this question are difficult: it could be, that males "feel" the Caya diaphragm more often, when they are informed its use. We have not valid data, if a

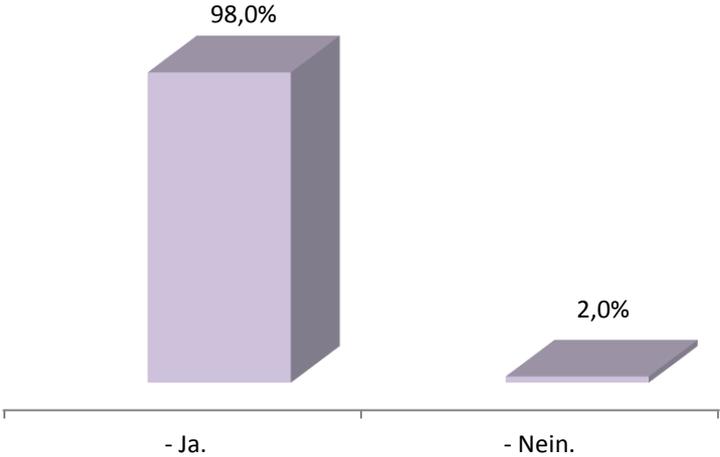
male would “feel” Caya diaphragm less often, if they were not informed about the use of a diaphragm before having sex.



Willing to recommend Caya to another woman?

98% of the participants said they would recommend Caya diaphragm to a friend. This suggests these women trust the Caya diaphragm—even though they are new users—and they are willing to share this message with others.

Figure 11. Willing to recommend Caya to another woman?



The results from this 2016 survey confirm and build additional evidence that Caya contoured diaphragm is appropriate for use by women of all ages and different stage in their life and relationships. The most important factor that motivates women to use Caya is looking for a non-hormonal method.

We hope to see more young women choosing Caya in the future. We will follow-up on this in the next survey in 2017.

Caya diaphragm is now becoming established in the German speaking markets (Germany, Austria and Switzerland). As women learn about this new non-hormonal method, the size of the Caya user group continues to grow. .

The company KESSEL medintim GmbH thank all women who have participated at this survey 2016. You help us and other women to learn more about the contraceptive method diaphragm and Caya.

Please contact us if you have questions or comments.

August 23rd 2016

Martin Kessel (CEO) and Antje Becker (QMB)