



Successful history of development: Caya® contoured diaphragm

Caya®

In 1885, the physician C. Haase alias Wilhelm Mensinga from Northern Germany could not foresee that his invention of the “occlusive pessary”, as the first diaphragm was called, would rise to new eminence in the early 21st century.

Between 1920 and 1960 diaphragms have been one of the most important contraceptives at the USA. During the last ten years, in research of new, non-hormonal contraceptives a foundation in the United States in cooperation with the famous CONRAD research institute (www.conrad.org) has designed a completely new diaphragm.

Under the research name “SILCS” (single-size contraceptive barrier device) this method was improved in evolutionary design with new materials, shapes and properties.

The round shape of the classic diaphragm was changed in favor of a more anatomical, oval shape. Instead of a spring of metal, nylon was selected for shaping. The silicone membrane is light (only 4 grams), easy to fold and insert.

The scientific support of this research was provided by CONRAD’s research group in Arlington (near Washington DC). For the first time, MRI images with the new diaphragm in the body were taken. Furthermore, fundamental issues of the adaptation of diaphragm size were addressed. It could be shown that the “SILCS” obviates the need for adaptation, as it fits most women.

Acceptance of the diaphragm method and thus the new Caya® diaphragm was determined in various countries, including Thailand and South Africa – even where the method had previously been completely unknown. The project is preliminarily completed with the safety study¹ with 450 couples at a total of 10 sites in the US. This multicentric study will be published shortly.

In 2010, the US foundation, which also controls the patents and the further research on SILCS, found a partner for manufacture and approval in Europe and the US: the company KESSEL Medintim GmbH is based in Walldorf near Frankfurt/M, Germany.

This company has specialized in the marketing of barrier contraceptives since 1987. It has assumed the task of evolving the completely researched and developed product into an approved, marketable barrier contraceptive. KESSEL is an ISO-13485-certified manufacturer of medical devices, qualified to develop the product “SILCS” into a marketable diaphragm: the “CAYA® contoured diaphragm”.

The Caya® diaphragm is manufactured in Germany and has received CE certification in March 2013. FDA clearance for the US was finished in August 2014. It is going to be launched at: Germany, France, Belgium, the Netherlands, Switzerland, Austria, Spain, Italy, Czech, Slovakia, Slovenia, Poland, Sweden, Norway, Finland, Denmark, Island, Luxembourg, Malaysia, Australia UK, Canada and other countries, in cooperation with local distribution partners.

¹ Schwartz et al.