

FemCap™
Earlier version; Obsolete
Second Generation; that is FDA Approved

Please note: Planned Parenthood report was based on the first generation *FemCap™* that was conducted with the obsolete earlier version first generation *FemCap™*.

How *FemCap™* was Tested

“In this study, an earlier version of the *FemCap™* that did not have the removal strap was being tested”

The pivotal clinical trials were conducted with an earlier version of the *FemCap* in ten universities in United States from 1995-1997. (See earlier version *FemCap* featured by Katie Couric of NBC Today Show in 1992).

<http://www.FemCap.com/multimedia.htm> , and visit www.femcap.com and click on News and go to Medical News and click on First generation FemCap (obsolete)
Based on this study the FDA approved **this earlier version** of the *FemCap* to be safe and effective for use by women of childbearing age to prevent or postpone pregnancy. Despite the fact that this **earlier version** of the *FemCap* was proven to be safe and effective in **the pivotal clinical trials**, we have learned that this first-generation device had two drawbacks.

First, poor effectiveness rate of the large 30 mm *FemCap* that is designed for women who delivered vaginally due to frequent dislodgement, **and** **Second** difficulty with the removal of the *FemCap*.

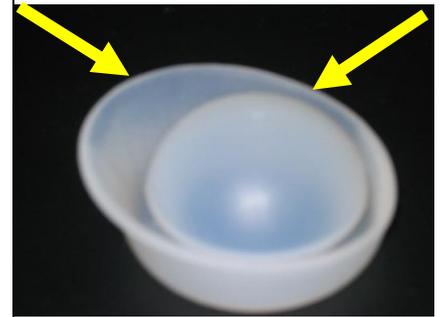
- 1) To compensate for the poor vaginal tone in women who delivered vaginally, *FemCap Inc.* increased the dimensions of the **brim** (pointed by the arrows) on the large 30 mm *FemCap*. This increased the surface area of contact between the **brim** and the vagina. This increased the stability and minimized dislodgment, thus enhancing effectiveness of the *FemCap* in women who delivered vaginally.
- 2) Added a strap over the dome of the *FemCap* to facilitate removal.

The second generation *FemCap* with the removal strap is the only device approved by the FDA for marketing.

To further enhance the effectiveness of the *FemCap* the FDA:

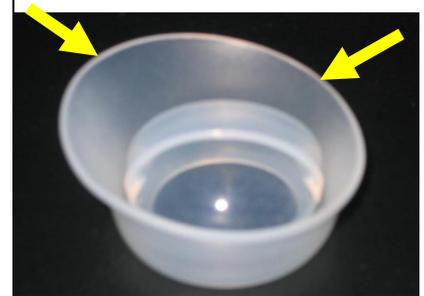
- 1) Strongly advised women to insert the *FemCap* prior to sexual arousal, every time to ensure correct placement over the cervix.
- 2) Recommended that women may use a back up method during the learning phase of the *FemCap*.
- 3) To use Emergency contraception as a back-up method **if** needed, in case the woman **has not** used the *FemCap* or used incorrectly.
- 4) Use the instructional video or DVD to supplement the verbal and the written instruction.

First generation
Earlier version *FemCap*



Obsolete now

Second generation *FemCap*

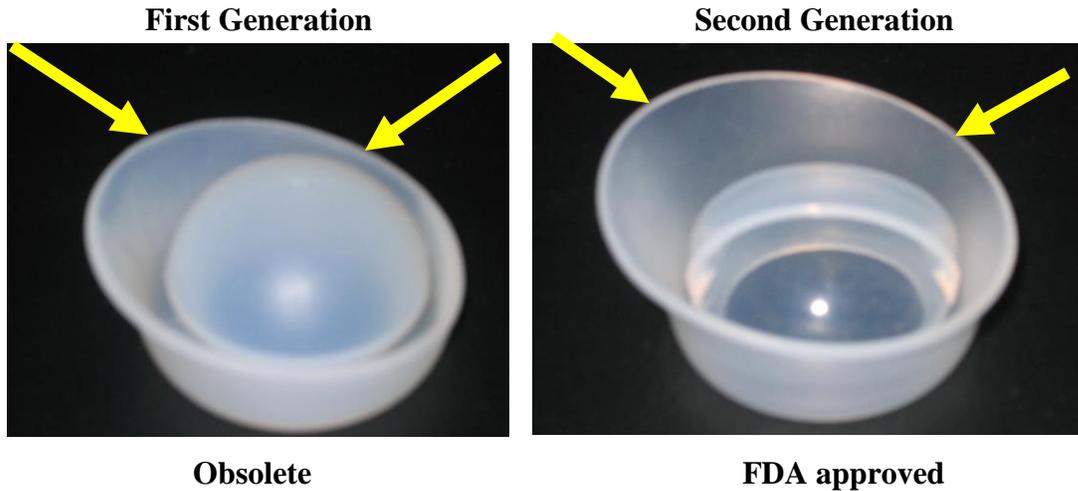


FDA APPROVED

Please visit
www.femcap.com
and click on FAQ

Effectiveness of the second
generation *FemCap*
And click on the references

The Rationale for modification from the First-generation to the second-generation FemCap.



Despite the fact that the first generation was proven to be safe and effective in the pivotal clinical trial, we have learned from the users that the first-generation device has two drawbacks. **First**, difficulty of removal of the FemCap, and **Second**, frequent dislodgement of the large 30 mm FemCap that is designed for women who delivered vaginally.

Since the FemCap is held in place by the vagina, it is obvious that the poor vaginal tone in women who delivered vaginally will decrease the support and stability of the FemCap, which will lead to dislodgment and thus poor effectiveness.

To address these two drawbacks the following design change was done:

- 1) A strap was added to facilitate removal.
- 2) To compensate for the poor vaginal tone in women who delivered vaginally, the dimensions of the brim (pointed by the arrows) were increased on the large 30 mm FemCap. This increased the surface area of contact between the brim and the vagina. This would increase the stability and minimize the dislodgment, thus enhancing effectiveness of the FemCap in women who delivered vaginally.

Result: The FDA approved ONLY the second-generation for marketing in the USA.

This is due to the enhanced safety, effectiveness and acceptability of the Second-generation.

Safety: The presence of the removal strap across the dome of the FemCap eliminates the potential of fingernail abrasion during removal.

Effectiveness: The increased dimensions of the brim (pointed by the arrows) would increase the the surface contact between the FemCap and the vaginal walls and hence the stability and thus the effectiveness of the large FemCap in women who delivered vaginally.

Acceptability: The ease of removal makes the FemCap user-friendly and significantly increased the acceptability of the FemCap.

NOTE: All the steps of design control from consumer request to the final release was followed according to the design control submitted

References:

http://femcap.com/news-articles/medical_news.htm#WHCJ

http://femcap.com/news-articles/medical_news.htm#Handbook

<https://books.google.com/books?id=Q4QbBQAAQBAJ&pg=PA383&dq=femcap&hl=en&sa=X&ved=0ahUKEwiy7Z795fPPAhVLq1QKHRjxAZAQ6AEIQDAD#v=onepage&q=femcap&f=false>