



HLL Lifecare Limited

HLL Lifecare Limited popularly known, as 'HLL' is a 55-year-old global organization, offering Contraceptives, hospital products, women healthcare products and healthcare services is headquartered at Trivandrum, South of India. HLL has today emerged as a leader in the area of contraceptives, hospital products, women healthcare products and healthcare services.

HLL's Women Healthcare Division offers a whole range of women healthcare products with a promise to provide total healthcare for women of all ages - addressing their social, emotional and physical wellbeing. WHD's product basket includes - Contraceptives, Ovulation Inducers, Antiemetic's, Menstrual Cycle Regulators, Antifibrinolytics, MTP Pills, Pregnancy Test Kits, Sanitary Napkins, Menstrual Cups, Sanitary Napkin Vending Machines & Incinerators, Natural Products like Galatogoge and Vaccines. It has a strong distribution network across the world.



Cool Cup from HLL

HLL's Menstrual Cup – Cool Cup- is a menstrual hygiene device that is inserted into the vagina during menstruation to collect menstrual blood. It is made of non-absorbent, reusable, platinum cured medical grade silicone and is considered as a safe alternative to disposable menstrual hygiene products. The bell-shaped cup seals against the vaginal wall just below the cervix. Depending on the amount of flow, every 6-12 hours, the cup is removed, emptied, rinsed, and reinserted. After each menstrual period, the cup requires sterilization by boiling in plain water. Even though M-Cups are proving to be an effective method, it is relatively unknown among the larger population due to lack of awareness and limited availability. Its multifold benefits include:

Reduction in carbon foot print by diversion of used sanitary napkins, reduced cost of waste handling & treatment and reduced risk to public health. Dignity of the persons handling urban waste is another important aspect.

Improved menstrual health & hygiene, privacy and convenience of use. Increased freedom of movement and activities including sports, work life etc.

Affordability due to reusability of M-Cups for up to five years

5000 M-Cups having a life span of a minimum of five years can result in:

Reduction in sanitary waste by 100 tonnes. Corresponding Carbon foot print reduction: 132.5 Tonnes of CO2 equivalent. Reduction of Rs10 lakh in sanitary napkin cost

Specifications

The menstrual cup provided by HLL is made of FDA approved medical grade silicone material. It is toxic free, durable, non-absorbent, hypoallergenic silicone containing no harmful additives. HLL's Cool Cup conform to UNFPA specifications.

Physical Requirements

- Comfort to use, dimensional stability and resilience to rebound.
- Ease of insertion and removal.
- Good tear strength and endurance to boiling, cyclic use and pulling out.
- Dimensional requirements

2 Bio Compliance standards

- HLL's Cool-Cup complies with:
- ISO 10993-10 (Mucosal Irritation)
 - ISO 10993-10 (Sensitization)
 - ISO 10993-5 (Cytotoxicity)
- ISO 10993-6 (Intra muscular implantation)
 - Directive 2011/65/EU- (ROHS)
- USP<88>CLASS VI tests Acute systemic toxicity

Dimensional Specifications

Dimensional Specifications of the Cool Cup conforms to the UNFPA specifications (2020).





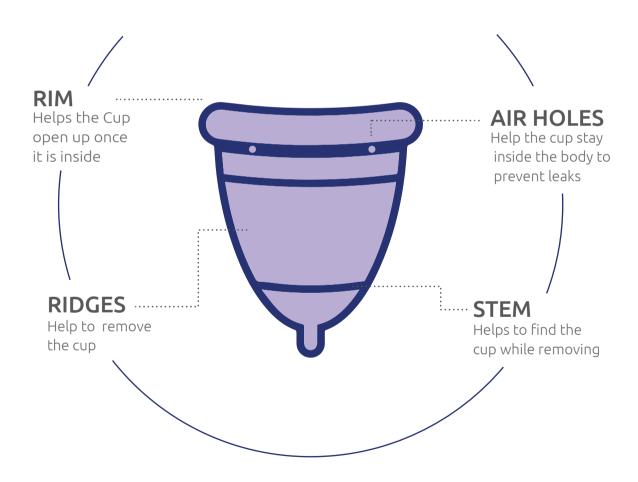
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Design of HLL Cool Cup



International Regulatory status

Regulatory control in different countries					
Country	Performance standards	Classified as Medical device	Post market surveillance	Device registration	Special labelling requirements
United States	Yes	Yes	Yes	Yes	Yes
Еигоре	Yes	No	Yes	No	No
Australia	Yes	Yes	Yes	No	Yes
India*	No	No	No	No	No

- In US, menstrual cups are classified as "Medical device".
 - In Europe, menstrual cups are classified as "Hygienic product"
 - In Australia, menstrual cups are classified as "Therapeutic device"

^{*}M-Cups qualify to be classified as a Class B medical device (Low moderate risk device under the Medical Devices Rules 2017, available under the provisions of the Drugs and Cosmetics Act, 1940)

How to Use Cool Cup

Step 1 - Wash your hands and cups

First wash your hands with a mild, un-perfumed soap and water like you would do before inserting a tampon without applicator.

Step 2 - Flatten your cup

Flatten your menstrual cup in a C fold or a punch down as illustrated between your thumb and other fingers to prepare for the fold.

Step 3 - Fold your cup

Once your menstrual cup is flattened, fold it in half with your other hand so that the rim makes a "c". Hold the cup firmly with the hand you are the most comfortable with. The folded part should face towards the inside of your hand as illustrated. There are several ways to fold your cup.

Step 4 - Prepare to insert

Spreading your legs, gently separate your labia with your free hand. Guide your folded cup rim first with the rounded end of the "U" shape facing you toward your vagina as illustrated. You can insert the cup while sitting, standing or squatting; Spreading your legs will facilitate insertion.

Step 5 – insert the cup

Once you inserted the rim of the menstrual cup, the cup will start unfolding itself the vagina. All you need to do to push it slightly with your finger until the whole cup is inside including the stem.it shouldn't sit too high, the bottom of your cup should be about half a finger away from the entry. Unlike a tampon, the cup is positioned in the lower part of vagina, but away, but beyond the pelvic bone.

Step 6- Rotate your cup

Lightly pinch the base of the cup (not the stem) and gently try to give it one full rotation in either direction. Doing so helps to avoid leaks by ensuring that the cup has opened fully. The cup should rotate easily when properly open. As an extra measure, though one that is usually unnecessary, you can check that it is fully opened by sliding a finger up next to the cup and feeling all the way around it.

Remove your cup

You can wear your cup safely up to 12h, if you have a heavy flow, you might want to empty it sooner. To remove the cup, first wash your hands in clean water and relax your muscles. Spreading your legs, gently separate your labia with your non-dominant hands. As if having a bowl movement, bear down lightly with your internal muscles. Doing so can help lower the cup, making it easier to grasp. Break the seal by squeezing the bottom part of the cup until you feel or hear the suction release. Now gently rock the cup from side to side while pulling down. Always pull the cup out while pinching the ridged bottom of the cup. Tip the contents into the lavatory, the toilet, bathtub, in the nature, anywhere you see fit.

Rinse and reuse

Wash the menstrual cup carefully, in water to clean it sufficiently before reinsertion. Please do not use soap or any other disinfectant to wash the cup, any residue on the cup may cause irritation. The cup should first be rinsed in cold water, so that menstrual blood does not stain the cup or make it develop an odor. When water is not available, it is okay to wipe the cup with toilet paper and/or a disinfecting wipe. You can give it a proper wash the next time.

After its use of your period, wash your menstrual cup carefully and store it in its own pouch or box provided with your cup. Do not store it in a hermetic container or plastic bag. The menstrual cup should be cleaned before and after your cycle and after emptying.

You need to sterilize your cup only once per cycle, at the beginning. While you are having your period you can simply rinse your cup with water. You do not need to sterilize it every time you reinsert it. The material of the cup has natural antibacterial properties, as your hands are clean it is perfectly safe.