

# Menstrual Cup Specifications

## General description

A reusable menstrual cup made of medical grade silicone, to be worn inside the vagina to collect menstrual fluid. The menstrual cup comes with a protective pouch and user instructions.

## Product description

Reusable menstrual cup (non-absorbent bell-shaped hygienic device) made of medical grade silicone, to be worn inside the vagina to collect menstrual fluid.

The cup creates a vacuum seal and is held in place by the walls of the vagina. Product comes with a protective textile pouch and user instructions. Workmanship and quality of the cup are declared by the manufacturer and allow in-use functionality for a minimum of 1 year.

Cup material: Medical grade silicone (may include elastomer, dye or colorant but no more than 0.5 per cent).

The material is comfortable to use, dimensionally stable and resilient to rebound. The cup will go back immediately to its original form after a prolonged period of use.

Material ensures easy insertion (easy to unfold in the vaginal cavity) and removal.

Material has good tear strength and endures boiling, cyclic use and pulling out.

Material is most often transparent but can come in different colors.

Material is hypoallergenic, non-absorbent and contains no harmful additives or chemicals.

The material, dye and colorants used are non-toxic, non-carcinogenic, non-mutagenic and do not cause skin irritation or skin sensitization.

Material is biocompatible and does not change performance after multiple uses (12 cycles).

Non-sterile.

Reusable for monthly use.

Shelf life minimum 5 years.

Easy to clean using the minimum quantity of supplies possible (e.g. boiled water in a pot or another container).

The cup must have a minimum of two air holes close to the rim and covering at least 2 sides.

Diameter of air holes is approximately 1 mm each.

Air holes have no sharp edges; the surface is smooth.

Cup wall thickness: 2 mm (+/- 0.3 mm).

Pull-out stem length: minimum 15 mm.

The pull out stem design allows firm grip for easy removal, easy spin and comfort during use.

The stem does not have a slippery surface, it is not hollow (for easy cleaning), and it does not have sharp edges.

Product comes with a protective textile pouch

May come with container for sterilization.

## Cup size

Small size for menstruators with light flow or a low cervix - especially young women/menstruators.

Outer (ext.) diameter of the rim: 36-40 mm.

Length of the cup excluding pull out stem: approx. 40-50 mm.

Cup capacity approx. 15-25 ml.

Firmness: Soft to Medium.

Medium size for adult menstruators.

Outer (exterior) diameter of the rim: 41-44 mm.  
Length of the cup excluding pull out stem: approx. 45-55 mm.  
Cup is able to collect approx. 20-30 ml.  
Firmness: Soft to Medium.

Large size for adult menstruators with a high cervix, heavy flow or after first child, vaginal delivery.  
Outer (ext.) diameter of the rim: 45-48 mm.  
Length of the cup excluding pull out stem: approx. 48-58 mm.  
Cup is able to collect approx. 30-40 ml.  
Firmness: Medium to hard

Note: Cup size, capacity, firmness and length vary by brand and the above size is therefore indicative only. The correct cup size depends on factors such as the individual anatomy of the user, user preference for cup firmness and the flow quantity.

### Supplied with

A washable, non-linting textile (e.g. cotton) pouch with a closing mechanism.  
The protective pouch is used for storing a cleaned cup during non-flow days.

### Accessories / Spare Parts / Consumables (available but not supplied)

N/A

### Instructions for use

Manufacturer's instructions for use (in English, Arabic, Spanish and French) should come with pictorial illustrations and/or drawings for folding and insertion.  
Instructions for Use (IFU) may include a QR code or a link to the video of instructions for use.  
IFU will include guidance for washing and sterilization.  
Instructions for storage and maintenance.  
Guidance for the appropriate time to empty and clean the cup (e.g. maximum 8 to 12 hours inside vagina), guidance for not using the cup during non-flow days of the cycle, guidance for leaking and guidance related to potential discoloration of the product.  
Instructions and warnings if irritation, discomfort, injury or a toxic shock syndrome is experienced by the user.  
Guidance on stem length adjustment, where applicable.  
Warnings to prevent sharing of the cup or cup use during sexual intercourse.  
Warning to prevent use if the cup is not properly washed/sterilized.  
The cup must be washed frequently in clean, boiling water as per manufacturer's instructions.  
Instructions should specify the manufacturer's recommendation for the maximum product life time (maximum time of use before replacement is required).

### Compatibility with IUDs

The IFU include the following precaution note:  
Women using Intra-uterine Devices (IUDs) for contraception should take caution as there have been scientific reports of menstrual cups having contributed to dislodging of the IUD.<sup>1</sup> Consultation with a

<sup>1</sup> Obstetrics & Gynecology: May 2020 - Volume 135 - Issue - p 1S  
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local health worker is advised. Women with IUDs may need to consider an alternative option for either family planning or menstrual flow management.

### Packaging and labelling

One (1) cup with a textile pouch in a protective primary packaging.  
Cup is individually placed in a sealed package between the factory and the end user.

Label includes:

Name and address of manufacturer  
Product name and description including any brand name  
Manufacturer's product code or reference number  
Product size  
Manufacturing and expiry date  
Lot/batch information  
Symbols used according to ISO 15223  
CE or FDA mark

### Regulation and Conformity Requirements

ISO 13485 or ISO 9001  
CE mark (CE self-declaration), or FDA registration, or MDSAP, or equivalent

### Classification

US FDA: Device class 2  
EU: Personal hygiene device

### Safety and product standards

Product must comply with following standards:  
ISO 10993-1  
ISO 10993-3  
ISO 10993-5  
ISO 10993-10  
Compliance to regulations related to the use of chemicals (e.g. REACH, SVHC in European Union).  
Materials: PhEur or USP pharmacopeia

### Environmental requirements

Sustainable, recycled, re-used or reusable materials for packaging, textile pouch and containers for storage and cleaning are preferred, and the manufacturer of the cup is preferably in compliance with or operates as per the principles of ISO 14001.