



# How to procure CycleBeads: a visual tool for the Standard Days Method

## A proven effective natural family planning method

June 2012

This advisory note has been prepared to explain the purpose of CycleBeads and the procedure that should be followed to procure them in accordance with a specification and quality-assurance assessment.

### What are CycleBeads?

CycleBeads (see Figure 1) is a visual tool that helps women use a fertility-awareness-based method known as the Standard Days Method (SDM), as an effective natural family planning method.

Georgetown University's Institute for Reproductive Health (IRH) has undertaken research to demonstrate the effectiveness of the SDM and development of the beads as a visual tool that supports its use (1).

The SDM helps couples identify the fertile days of a woman's menstrual cycle. It can be used to plan or prevent pregnancy and in combination with abstinence or barrier methods during the fertile days. In accordance with guidance included in the World Health Organization's (WHO's) *Medical eligibility criteria for contraceptive use, 2010* (2), there are no medical conditions that become worse as a result of using fertility-awareness-based methods, such as SDM. In general, these methods can be provided without concern for health effects on the people who choose them. However, there are a number of conditions, for example being postpartum or perimenopausal, that make their use more complex. The existence of these conditions suggests that; (1) use of these methods should be delayed until the condition is corrected or resolved; or, (2) to ensure correct use, clients will require special counselling, possibly by a more highly trained provider.

WHO recognizes SDM as an evidence-based practice, and it is included in the "Fertility awareness" chapter of Family planning: a global handbook for providers (3) and in the *Medical eligibility criteria for contraceptive use* (2).

The United States Agency for International Development (USAID) includes SDM among high-impact practices in family planning (4).

Figure 1. CycleBeads



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## How do the beads work?

CycleBeads help a woman determine the days of her menstrual cycle in which she is most likely to become pregnant. It is a tool that is simple to use and consists of a colour-coded string of beads, with a rubber ring. When the woman starts her period, she moves the rubber ring to the red bead. She then continues to move the ring one bead each day, always in the direction of the arrow. As long as she is on the brown beads, the likelihood of her becoming pregnant is very small. When she is on the white beads (days 8–19 of the menstrual cycle), she has a high probability of becoming pregnant if she has unprotected sexual intercourse. The method is most appropriate for women who have cycles that are regular and usually range between 26 and 32 days in length.

Research has shown that Standard Days Method used with CycleBeads is:

- more than 95% effective (1, 5)
- free of side-effects
- easy to use (1, 5)
- inexpensive and long lasting
- educational

The beads help a woman track her menstrual cycles and assist couples in communicating about when to avoid unprotected sexual intercourse. The method does not protect against sexually transmitted infections. During fertile days, the couple should either abstain from sexual intercourse or use a barrier method, such as a condom, unless they have decided that a pregnancy is wanted.

## Procurement

Family planning programmes in many countries now include SDM as part of the contraceptive method mix they offer their clients, within the context of providing a service based on informed choice.

Although the beads are not, as yet, included in the Interagency List for Essential Medical Devices for Reproductive Health, it is proposed that they are included and classified as a renewable/consumable when the document is revised, since the beads:

- should be available at the country level to help programmes meet the needs of a broad range of family planning clients;
- will be procured by the United Nations Population Fund (UNFPA) if requested and funded through the ministry of health and/or bulk procurement and/or international agency;
- are also offered as part of the contraceptive method mix available through the Central Contraceptive Procurement (CCP) Project of the Commodities Security and Logistics (CSL)

Division at USAID, and can be ordered by USAID programmes alongside other contraceptive methods. USAID missions can provide funding requests for procurement of the beads to the CCP project, either as field support or as a modified acquisition and assistance request document. Orders should be forwarded to the CSL country backstopper.

## Specifications

A specification is a statement of the buyer's requirements. The beads should be procured from a licensed manufacturer in accordance with the specification shown in Table 1.

## Quality assurance

It is recommended by the WHO Department of Reproductive Health and Research that procurement agencies undertake a preshipment compliance test by taking a random sample of 20 products for visual inspection, to ensure they all comply with the specification prior to shipment. This is equivalent to an acceptable quality level (AQL) of 0.65. This means that over time, no more than one in approximately 200 CycleBeads will be incorrectly assembled.

When inspecting CycleBeads, the following attributes must be assessed:

- that the string is double stranded and free from any fraying or damage;
- that the string knot is secure and resists slipping;
- that the beads are tear shaped with no rough edges or sharp mould flash;
- that the correct number of beads are mounted on the string in the correct order;
- that an O-ring is mounted on the string;
- that the O-ring can be moved relatively freely from bead to bead but is not so loose that it can be accidentally displaced by the user;
- that an extra O-ring is provided with each set of beads;
- that there is a clasp present;
- that the two parts of the clasp can be unscrewed and then securely refastened together;
- that the labelling complies with the agreed specification for the product;
- that an instruction leaflet is supplied with each set of beads and the instructions comply with the specification, taking into account any particular requirements itemized in the purchase specification.

All 20 sets of beads that are inspected must comply with these requirements.

- Further information about the procurement of CycleBeads can be obtained from the IRH web site: <http://www.irh.org/?q=content/how-use-cyclebeads>

**Table 1. Specification for CycleBeads**

Component	Description	Means of verification
The beads	<p>32 tear-drop-shaped coloured beads with no rough edges on a non-detachable double durable string.</p> <ul style="list-style-type: none"> <li>• 1 black rubber O-ring, which moves freely from one bead to the next bead. The beads are arranged in the following sequence:</li> <li>• a red bead to signify the start of the menstrual period</li> <li>• followed by 6 brown beads, which still signify safe days</li> <li>• followed by 12 white beads, which now signify days when the woman is likely to get pregnant. To prevent pregnancy, no unprotected coitus should take place</li> <li>• followed by 7 brown beads, which refer to days when the woman is not likely to get pregnant</li> <li>• followed by 1 dark brown bead, which notes if a cycle is less than 26 days</li> <li>• followed by 5 brown beads, beyond which time, if menses have not begun, the woman has a cycle more than 32 days.</li> </ul> <p>Pigments used with coloured beads should be suitable for use in medical devices.</p>	Visual inspection
The clasp	The clasp is a screw clasp that allows the user to replace the O-ring if it breaks or becomes difficult to move.	Visual inspection
Instruction leaflet	<p>Instructions leaflets should be included in the packaging. Instructions for use, for both literate and low-literacy users, can be found at: <a href="http://archive.k4health.org/toolkits/sdm/cyclebeads%C3%82%C2%AE-inserts">http://archive.k4health.org/toolkits/sdm/cyclebeads%C3%82%C2%AE-inserts</a></p> <p>Instructions should be provided in the language specified by the procuring body.</p>	Visual inspection
Packaging and labelling	<p>The colour, print design and identification markings, including Pantone references and font sizes, should be as specified by the buyer, and annexed to this specification.</p> <p>Labelling must specify the name of the product, lot number and date of manufacture.</p> <p>Individual packages must be square or circular and must not distort the rolled beads. The package should be hermetically sealed.</p>	Visual inspection

## References

1. Arévalo M, Jennings V, Sinai I. Efficacy of a new method of family planning: the Standard Days Method. *Contraception*, 2002, 65:333–338 (<http://archive.k4health.org/system/files/Efficacy%20SDM%202002.pdf> accessed 1 June 2012).
2. *Medical eligibility criteria for contraceptive use*. Geneva, World Health Organization, 2010.
3. World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), INFO Project *Family planning: a global handbook for providers*. Baltimore and Geneva, Center for Communications Programs and World Health Organization, 2008.
4. United States Agency for International Development (USAID). The Standard Days Method®: expanding family planning options. *Repositioning in Action E-Bulletin*. ([http://www.usaid.gov/our\\_work/global\\_health/pop/techareas/repositioning/repfp\\_ebulletin/021709\\_en.html](http://www.usaid.gov/our_work/global_health/pop/techareas/repositioning/repfp_ebulletin/021709_en.html), accessed 1 June 2012).
5. Gribble et al. Being strategic about contraceptive introduction: the experience of the Standard Days Method®. *Contraception*, 2008, 77:147–154 (<http://archive.k4health.org/system/files/Being%20Strategic.%20Contraception%202008.pdf> accessed 1 June 2012).

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WHO/RHR/12.14

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