

# Female Condom Technical Review Committee Summary report on FC2

## Introduction

The Female Health Company has developed a new female condom made from synthetic rubber latex. At present the condom is identified as FC2 (the original Reality® condom made from polyurethane now being referred to as FC1). The synthetic rubber latex is a terpolymer of butadiene, acrylonitrile and methacrylic acid, commonly referred to as nitrile rubber, which is widely used for making medical examinations gloves. A specific grade of latex was chosen to allow the properties of FC2 to match, as far as possible, those of FC1.

FC2 is made by a dipping process that is very similar to the method used for making male latex condoms and medical gloves. The outer ring is made by rolling down the latex film on the former in much the same way as a bead is formed on a latex male condom. The inner ring remains unchanged from that used in FC1. The Female Health Company expects the manufacturing cost of FC2 to be significantly lower than the FC1 whilst essentially maintaining equivalence with respect to safety, performance and efficacy.

Currently, there is no international standard for female condoms (International Standards Organization Technical Committee ISO/TC/157 is developing a standard but it is unlikely to be published for at least another two years) so the effectiveness and safety of each design has to be evaluated by experts on an individual basis. Given this situation, the United Nations Population Fund (UNFPA) requested the World Health Organization, Department of Reproductive Health and Research, to review the second-generation synthetic latex female condom (FC2) produced by the Female Health Company as well as the Reddy Latex Female Condom manufactured by Medtech Products Limited, and provide guidance on whether these products can be included in the UNFPA public-sector procurement programmes.

A team of internationally recognized technical experts and advisers, the *Female Condom Technical Review Committee*, was established by the WHO Department of Reproductive Health and Research, January 2006, to conduct the review. The technical experts were experienced in condom research, design, manufacture and testing as well as public-sector procurement, the regulation of female condoms and conducting clinical trials on condoms. Technical advisers selected from organizations and regulatory bodies with particular interest in male and female condom development, regulation and marketing, also participated in the review.

The Female Health Company submitted a comprehensive, multi-volume dossier, which included details of a clinical failure mode study comparing FC1 and FC2. The dossier was reviewed by the *Female Condom Technical Review Committee* against agreed assessment criteria. The Committee drafted recommendations and submitted a confidential report to the Female Health Company with a request that further information be provided to the Committee in order to clarify issues raised during the technical review process. The Committee agreed to review in accordance with the agreed criteria any additional material submitted by the Female Health Company in response to the confidential report. The WHO Department of Reproductive Health and Research co-ordinated this continuing review process and was responsible for collating the recommendations of each expert and responding to the manufacturer.

## Summary of the outcome of the review process

### Design

The choice of materials and general product design are considered acceptable. Toxicity tests according to ISO 10993 parts 5 and 10 have been done on the finished condom and

the results appear to be equivalent to those for a latex male condom used as a control.

The design itself, which is essentially the same as FC1, did not give rise to any specific testing requirements. The viral barrier properties of FC2 have been assessed and are satisfactory. Some questions were raised about the intended timing of insertion of the product prior to intercourse but these were subsequently addressed satisfactorily by the company.

#### **Products Specification**

The product specification is largely based on that for FC1. Some questions about the specification and test methods were referred back to the company including a request for further justification for the limits for airburst pressure and volume in the specification. In particular, the Committee sought to ensure that the specification for FC2 is at least as demanding as the requirements specified in the standard for male latex condom (ISO 4074: 2002). The Female Health Company responded by revising parts of the specification and some test methods to address the issues raised.

#### **Manufacturing and Packaging Process**

Given that the product has only been produced in pilot quantities to date and the full manufacturing strategy remains to be finalized, there were some questions relating to the appropriateness of ISO certificates and related audits. The female Health Company has agreed that these will be resolved before full production starts. It was accepted by the Committee that the manufacturing process and provisions for quality assurance are acceptable.

#### **Product and Process Validation**

To date, only limited validation studies have been undertaken but a commitment to ongoing validation as the process moves from a pilot operation to full production has been made by the company. Current stability studies suggest that the product will have a satisfactory shelf-life on the basis of ongoing accelerated studies at elevated temperatures. The company agreed to start real-time stability studies at 30°C/65%RH (relative humidity) immediately to confirm the shelf-life claims. Pending the outcome of further stability studies the company agreed to reduce the

claimed shelf-life of the product to three (3) years, on an interim basis.

#### **Clinical Review**

Although no contraceptive or STI prophylaxis studies have been completed, FC2 has been assessed for performance and acceptability in a randomized cross-over trial against FC1 among South African women by the Reproductive Health Research Unit (RHRU), Durban. The trial was designed to compare clinical failure modes for the two products. With over 200 women completing the study and a total of 1,910 FC1 and 1,881 FC2 condoms being used the study was considered to have adequate power to allow a reliable comparison of the failure rates to be made. The total clinical failure rate was 97 events from 1,910 uses of FC1 (5.1%) and 78 events from 1,881 uses of FC2 (4.2%). The comparative trial of failure modes suggests therefore that the two devices are functionally equivalent, when used correctly.

Safety and acceptability data from the trial are reassuring and suggest that the incidence of adverse reactions experienced was no greater with FC2 than FC1. These findings support the claim that the two devices are very similar. There were a few reports of women experiencing a burning feeling, rash or itching following FC2 use but there was no obvious explanation for these reported reactions and given the acceptable results from the toxicity testing the findings were not considered significant.

### **Conclusions**

The Committee concluded that FC2 is in principle being manufactured to a least the same standard as the polyurethane female condom FC1. In addition, the design and physical characteristics of FC2, supported by the clinical data, suggest that the two devices are functionally equivalent, when used correctly. Based on this assessment FC2 is considered acceptable for bulk procurement by UN Agencies subject to the standard quality assurance measures being applied prior to procurement recommended by WHO/UNFPA/UNAIDS *Male Latex Condom: Guidelines for Procurement*, Geneva, 2004. In addition, WHO and UNFPA will undertake an independent inspection of the manufacturing facilities, once production of FC2 and/or component parts has been fully established. (1)

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