A DAPIVIRINE RELEASING CONTRACEPTIVE DIAPHRAGM

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The PATH SILCS Diaphragm

- One size fits most diaphragm – no need for a clinician.
- Consists of a thermoplastic spring core, overmoulded with a silicone sheath.
- Phase 2/3 study shows SILCS to be a safe and effective contraceptive diaphragm.
- Commercialization partner preparing regulatory applications in Europe and USA.
- First production run beginning for European Market. (2012)
- Phased introduction of the product in both developed and developing countries.

Figure 1. SILCS diaphragm.
Figure 2. Thermoplastic core.
Figure 3. Core *in situ*.
Microbicide Releasing Diaphragm

- Development over four years from first principles to POC.
- Replace nylon SILCS core with POM core.
- Full-scale production facility at QUB (installed 2011).
- Replacement by POM and addition drug does not affect mechanical performance.
- Therefore, should not affect contraceptive efficacy.
Results – *In Vitro* Release

- 10% (w/w) DAP loaded spring-cores and diaphragms. (110mg)
- 200ml Isopropanol:water (1:1); daily/weekly replacement.
- Spring-core only (**matrix**) released 60mg over the 28 day period.
- Diaphragm (**reservoir**) released 3.8mg over the 28 day period. (131μg/day)
- Over six months, release was 30mg at 174μg/day.
- Release comparable to IPM reservoir silicone ring. (135μg/day)