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| --- | --- | --- | --- |
| **Characteristics** | | **Healthy Volunteers (n=10)** | |
| Age, median (range) | | 46.0 (28-70) | |
| Race | |  | |
| White | | 8 (80%) | |
| Asian | | 2 (20%) | |
| Parity, median (range) | | 2 (0-3) | |
| Vaginal Parity, median (range) | | 1.5 (0-3) | |
| Vaginal Estrogen Use | | 2 (20%) | |
| History of Hysterectomy | | 0 (0%) | |
| History of vaginal reconstructive surgery | | 0 (0%) | |
|  | | | |
| Comfort of use (1= very poor, 5 = very good), median, (range) | |  | |
| Active wearing | | 4.5 (1-5) | |
| Device removal | | 4.5 (2-5) | |
| Time of use daily, median (range) | | 2.5 (1-8) hours | |
| New symptoms reported after use | |  | |
| Vaginal Pain | | 2 (20%) | |
| Vaginal Discharge | | 1 (10%) | |
| Vaginal Bleeding | | 1 (10%) | |
|  | | | |
| **Feedback Through Steps of Use, median (range)** | **Insertion** | **Locating Loop for Removal** | **Removal** |
| How intuitive did you find this task? (1= very difficult, 5= very straightforward) | 4 (1-5) | 5 (4-5) | 5 (5) |
| How easy-to-use did you find the device? (1= very difficult, 5= very easy) | 4 (1-5) | 5 (4-5) | 5 (4-5) |
| How safe did you find this task? (1=high risk, 5= very safe) | 5 (4-5) | 5 (3-5) | 5 (4-5) |
| **Sample of free form answer questions asked of the healthy volunteers for feedback:** | | | |
| Did you have any changes in your ability to urinate or defecate? Please explain.   * 2 reported slower urine stream, but did not affect ability to empty bladder. * No changes in defecation reported. | | | |
| Did you have any feeling of possible expulsion with use of the device during daily activity? If yes, please explain.   * 1 reported device shifted lower in vagina with full bladder | | | |
| Please provide your thoughts on tolerance of this device by patients who are two weeks post-operative from reconstructive vaginal surgery.   * 6 reported insertion/removal of device could be uncomfortable in early post-operative setting. * 7 reported once device was properly placed, the device was no longer noticeable during active use. | | | |
| Please provide your thoughts on how to improve the device or its application/removal   * 6 of responses posed a change to the softness or shape of the retaining feature. * 3 of responses mentioned more descriptive instructions for use and orientation of device. | | | |

\*over 2 consecutive days total