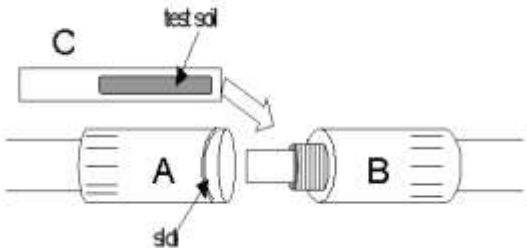


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|--|---|
| Brand Name of Product | LumCheck™ |
| Generic Name of Product | Cleaning challenge device for minimally invasive surgical (MIS) instruments washers/ultrasonic utilizing pulse/retro flow cleaning. |
| Product Code Number(s) | WLC-101, WLC-102 |
| Purpose of Product | To provide a standardized challenge to cleaning function of pulse/retro-flow washer/ultrasonic for rigid-channeled/lumened items, including MIS instrument. |
| Range of Applications for Product | For use in instrument washers with a pulse/retro flow cycle. |
| Key Specifications of Product | <ul style="list-style-type: none"> • Test coupon with a test soil comprised of blood proteins typically found inside of clinically used MIS and other lumened/channeled items coming in contact with the vasculature system during clinical use. • Single channel lumen holder designed as a surrogate to the internal channel of an MIS instrument or other lumened items. The holder unscrews for placement of the test coupon. |

| Shipping & Storage | |
|---|---|
| Shipping Conditions & Requirements | N/A |
| Storage Conditions | Store in the protective foil pouch at 2 – 25 °C |
| Packaging Contents | <ul style="list-style-type: none"> • Each coupon is placed in an individual water-tight foil pouch • 25 tests per box • Holder sold separately |
| Shelf Life | 18 months from date of manufacture. (Consult package for expiration date.) |

| Instructions for Using Product | |
|---------------------------------------|---|
| Description of Use(s) | To challenge the cleaning function of pulse/retro-flow washer/ultrasonic with a standardized soil test inside a surrogate device. |
| Preparation for Use | N/A |
| Diagrams (drawings, pictures): |  |
| Steps for Use of Product | <ol style="list-style-type: none"> 1. Unscrew the LumCheck™ holder. 2. Detach part A (marked with “slot”) from part B. 3. Open protective pouch of LumCheck™ and insert the test coupon (part C) in part B. Do not touch the area covered with the test soil. 4. Close LumCheck™ holder by screwing part A to part B. 5. Connect the holder with one of the channel irrigation systems of the washer (luer-lock). 6. Start the wash cycle according to the manufacturer’s IFU. 7. At the end of the cycle, retrieve the holder from the washer. 8. Open the holder by unscrewing part A from part B and remove the test coupon without touching the soiled areas. 9. Visually inspect the coupon for residual soil. Compare the test to the interpretation chart, WT-104, scale (0-5). |

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| Interpretation of Results | If less than optimal results were obtained ("Steps for Use of Products" 1-5), make adjustments to the equipment utilizing the chart (WT-104) as a guide. Typical failures can be caused by: <ul style="list-style-type: none"> • Insufficient detergent due to empty containers • Detergent pump failure or clogged delivery tubing • Poorly functioning water pump • Incorrect water temperature • Incorrect cycle settings. |
| Contraindications of Test Results | N/A |
| Documentation | Record results on log sheet located on hmark.com |
| Special Warnings and Cautions | N/A |
| Disposal | Dispose of in a biohazard container. |

| Reprocessing Instructions | |
|---|-----|
| Point of Use | N/A |
| Preparation for decontamination | N/A |
| Disassembly Instructions | N/A |
| Cleaning – Manual | N/A |
| Cleaning – Automated | N/A |
| Disinfection | N/A |
| Drying | N/A |
| Maintenance, Inspection, and Testing | N/A |
| Reassembly Instructions | N/A |
| Packaging | N/A |
| Sterilization | N/A |
| Storage | N/A |
| Additional Information | N/A |

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| Related Healthmark Products | TOSI® |
| Other Product Support Documents | ProFormance™ Brochure, ProFormance™ Price List, |
| Reference Documents | LumCheck™ Videos, LumCheck™ Log Sheet, LumCheck™ Example Policy, Instructions for Ultrasonic & Lumen Tests |
| Customer Service Contact | Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com |

2021-11-12 Ralph J Basile