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# Stryker's reprocessed MyoSure tissue removal devices (MyoSure, LITE, REACH, XL, XL-Fluent): **a preclinical comparison to Hologic's tissue removal suite**


## Authors

**Nicholas Ferentheil, BSE**
Research and Development

**Brooke McDonald, BSBME**
Research and Development

## Testing facility and clinical staff

**Debra Wickman, MD, Banner**
University Medicine Womens Institute

**Robert Phillips, MD, FACOG**
Banner Thunderbird Medical Center



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## Comparative Study

### Study Purpose

Backed by over ten years of clinical use, the MyoSure tissue removal suite has been a trusted and valued product in the hysteroscopic removal of fibroids, polyps and retained products of conception.

Through the process of disassembly, cleaning, remanufacturing, functional testing, packaging and sterilization, we have enabled an additional clinical use of the MyoSure tissue removal device suite. Through ex vivo laboratory testing and physician assessment, our devices were rigorously compared to Hologic's devices, where they were deemed to be statistically equivalent across all measures.

### Methods

This study compares the performance of Hologic's MyoSure tissue removal devices (MyoSure, LITE, REACH, and XL) to our Stryker reprocessed MyoSure tissue removal devices in laboratory testing (tissue removal performance, suction performance and reliability).

Physician-evaluated user needs of our devices utilized the aforementioned ex vivo laboratory tissue removal test methodology.

### Results

Ex vivo laboratory studies revealed statistically equivalent performance in comparing tissue removal performance and suction performance. Additionally, testing of our Stryker devices after 63 minutes of continuous device activation resulted in no appreciable degradation of the cutting performance.

Furthermore, gynecological physicians evaluated our reprocessed MyoSure tissue removal devices for key user needs and unanimously deemed the devices satisfactory.

# Clinical implications

## Ex vivo laboratory testing: Tissue removal performance

The tissue removal performance test assessed the duration required for the device to resect a fixed weight of tissue; 15 grams for the MyoSure, LITE and REACH models; 70 grams for the XL model. Laboratory tissue removal performance was conducted ex vivo to ensure an accurate comparison between Hologic and Stryker devices via the control of the tissue weight, type, location, the fluid in-flow/out-flow rates, and intrauterine pressure. A total of 164 tissue removal tests were conducted in support of the laboratory testing across both available fluid management systems, Aquillex and Fluent. Of the 164 tests, 100 tests were conducted using Stryker devices and 64 were conducted using Hologic devices. The median tissue removal durations were statistically equivalent between Hologic and Stryker devices. The minimum and median tissue removal durations observed during testing are as follows:

### Tissue removal performance – minimum duration

| | MyoSure | LITE | XL | REACH |
|---|---|---|---|---|
| SSS | 2 min 27 sec | 2 min 43 sec | 7 min 11 sec | 2 min 28 sec |
| Hologic | 2 min 19 sec | 2 min 31 sec | 8 min 17 sec | 2 min 27 sec |

### Tissue removal performance – median duration

| | MyoSure | LITE | XL | REACH |
|---|---|---|---|---|
| SSS | 2 min 56 sec | 3 min 38 sec | 11 min 13 sec | 3 min 6 sec |
| Hologic | 2 min 51 sec | 3 min 17 sec | 9 min 10 sec | 2 min 58 sec |

## Suction performance

The suction performance test utilized a high accuracy pressure transducer and custom LabVIEW software to measure the period in which a device's suction is reduced from an operational vacuum pressure to atmospheric pressures, when the external vacuum source (i.e. Aquilex or Fluent) was turned off. This allowed for a controlled comparison of Hologic and our Stryker devices using fixed start and end vacuum pressures to quantify the rate at which the devices leak.

A total of 169 devices were tested, comprising 118 Stryker devices and 51 Hologic devices. Stryker devices demonstrated suction decay test results within specifications derived from the benchmarking of Hologic devices. The maximum and median suction decay durations observed during testing are as follows:

### Suction performance – maximum seal duration

| | MyoSure / LITE/ REACH | XL |
|---|---|---|
| SSS | 1 minute 52 seconds | 47 seconds |
| Hologic | 1 minute 53 seconds | 42 seconds |

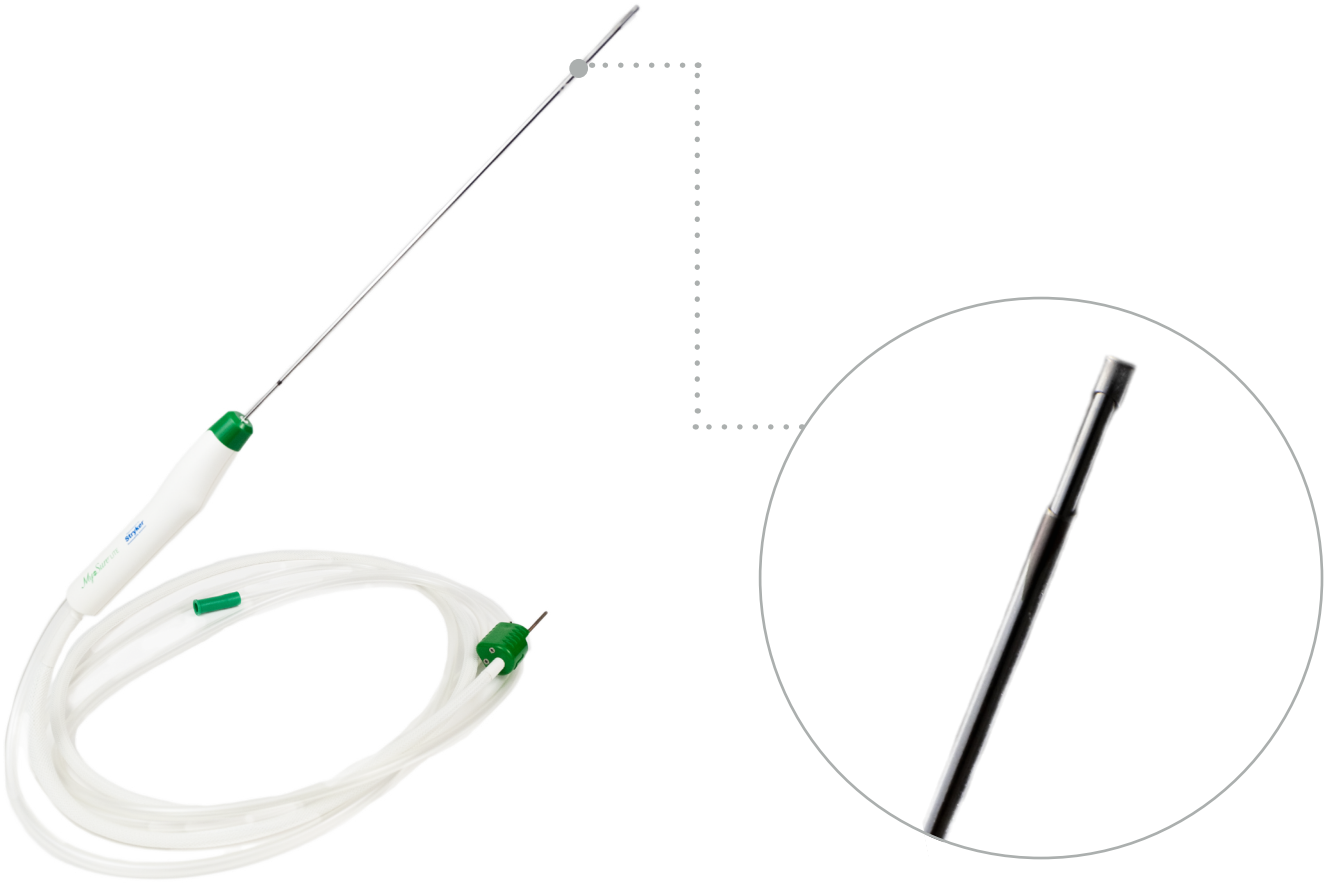
### Suction performance – median seal duration

| | MyoSure / LITE/ REACH | XL |
|---|---|---|
| SSS | 1 minute 9 seconds | 29 seconds |
| Hologic | 1 minute 21 seconds | 33 seconds |

## Reliability

To determine whether device functionality declines as activation and tissue removal increases, a total of 23 Stryker reprocessed MyoSure tissue removal devices were used to assess tissue resection capability after 63 minutes of device activation and tissue removal. Comparatively, reliability testing performed by Hologic demonstrated tissue resection capability after 30 minutes of device activation and tissue removal.

All 23 Stryker reprocessed devices maintained full capability of tissue removal after 63 minutes of device activation and tissue removal, demonstrating reliability for durations longer than tested by Hologic.



## User validation

Our reprocessed MyoSure tissue removal devices proved satisfactory in both performance and usability through an assessment by three physicians with over 85 years of combined experience in Gynecology. The physicians participated in ex vivo laboratory tissue removal testing and overall performance assessments to evaluate the ability of the device to meet the users' needs such as: aesthetics, misuse/patient harm prevention, compatibility and tissue targeting and resection. For each user need addressed, the physicians unanimously awarded satisfactory results to the Stryker reprocessed MyoSure devices.

## Discussion

Rigorous laboratory testing demonstrated that Stryker reprocessed MyoSure tissue removal devices perform as safely and effectively Hologic MyoSure tissue removal devices. Certain factors drive device functional performance equivalency. Factors, such as the controller used to drive the cutting shaft rotation and reciprocation, as well as the fluid management system used to control and modulate the suction pressure, intrauterine pressure and fluid flow rate, transmit the necessary inputs through the device. A key component in delivering consistent performance is the reprocessing and comprehensive testing sequence that Stryker devices undergo. Stryker disassembles MyoSure tissue removal devices to their base components, which facilitates a multi-point inspection on each of the components. Any substandard parts are rejected. During reassembly, the drive cable, shroud and suction/outflow tubing are replaced with new components. The OEM shroud is replaced with a bio-based plastic composed with Tenite Cellulouse, which is made with a renewable softwood material. The OEM polyvinyl chloride (PVC) tubing is replaced with non-PVC tubing. Once reassembled, our reprocessed devices are then subjected to simulated-use testing, which includes device activation on OEM controllers and suction performance. Our reprocessed devices, which all bear the Stryker label, then would have had each component pass every inspection step. Fully assembled devices have also been individually verified to perform as intended. Beyond in-line performance testing, another FDA 510(k) requirement is to submit validation studies on cleaning, sterilization and functional performance. For medical device manufacturers like Stryker, this means testing the tolerances of OEM devices and demonstrating a reprocessed device will be at least as safe and effective.

## Conclusion

As indicated by the 510(k) clearance, the FDA has determined that our reprocessed MyoSure tissue removal devices are substantially equivalent, or as safe and effective, as devices manufactured by Hologic. The ex-vivo laboratory studies presented in the paper validate that the functional performance of reprocessed Stryker MyoSure devices is statistically equivalent to Hologic manufactured MyoSure tissue removal devices.

# References


1. Based on Internal Stryker Validation Test Report on File TR19605, independent physician evaluation of the Reprocessed MyoSure Tissue Removal Devices

2. Based on Internal Stryker Functional Test Report on File TR19603, internal benchtop testing conducted utilizing Reprocessed MyoSure Tissue Removal Devices

3. Based on Internal MyoSure DV Functional Leak Decay Statistical Analysis on File DHFD15327