

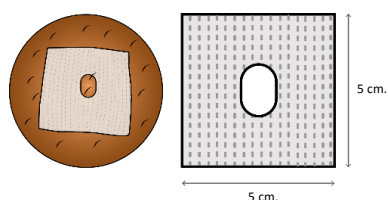
BACKGROUND- Skin safety and integrity is a challenge for wound dressings that rely on adhesive patches to maintain a secure seal. Frequent changes and need for an air or watertight seal requires the use of an advanced adhesive to maintain epidermal safety and device efficacy. Qivi - Male External Urine Management Device adheres securely with a silicon-based adhesive patch. The adhesive patch conforms around a range of anatomical sizes, provides a secure seal, and maintains the microclimate at the urogenital area.

METHOD- A comprehensive functional test was conducted to determine the safety and efficacy of Qivi's novel adhesive patch. Ten (10) subject volunteers (5 male and 5 females) with different skin types, diverse follicle density and sebum levels were chosen to participate in a 2-phase test.

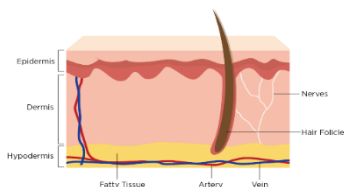
Phase – 1 was conducted to evaluate the effect of Qivi's novel silicon-based adhesive on the epidermis with repeated use for a period of 5 days. The subjects volunteered to wear a patch sized 5x5cm at the antecubital fossa and the wrist, which were replaced every 12-hours. A total of 10 adhesive changes were performed on all 10 subjects/volunteers.

Phase – 2 was conducted to evaluate the performance and efficacy of the adhesive, by applying the patch for 24 hours, which is twice as long as the prescribed duration of use. The subjects volunteered to wear another patch sized 5x5cm at the same locations and performance was evaluated by inspecting the integrity of the circumferential seal at the end of the evaluation period.

After each adhesive application, a 1-Kg roller was applied to ensure uniform application pressure, and a Universal Testing Machine was used to ensure consistent removal force. Dermal redness, irritation, effect on hair follicles and circumferential seal were documented during the study. None of the adhesive patches were removed prior to the designated period and the data for each volunteer was included in the consolidated result.



Adhesive Patch 5x5 cm
at the Cubital Fossa



Skin Safety & Efficacy Test					
VOLUNTEERS	REDNESS OBSERVED	DERMAL IRRITATION	EFFECT ON HAIR FOLLICLES	PERIOD OF APPLICATION	SKIN SAFETY & EFFICACY
1	NO	NO	2-3 hair follicles protruded*	120 Hrs.	<p>100% safe and effective</p> <p>*Note- Trimming/ clipping required in case of moderate to excessive pubic hair</p>
2	NO	NO	NO	120 Hrs.	
3	NO	NO	NO	120 Hrs.	
4	NO	NO	NO	120 Hrs.	
5	NO	NO	1-2 hair follicles protruded*	120 Hrs.	
6	NO	NO	NO	24 Hrs.	
7	NO	NO	NO	24 Hrs.	
8	NO	NO	2-3 hair follicles protruded*	24 Hrs.	
9	NO	NO	NO	24 Hrs.	
10	NO	NO	NO	24 Hrs.	

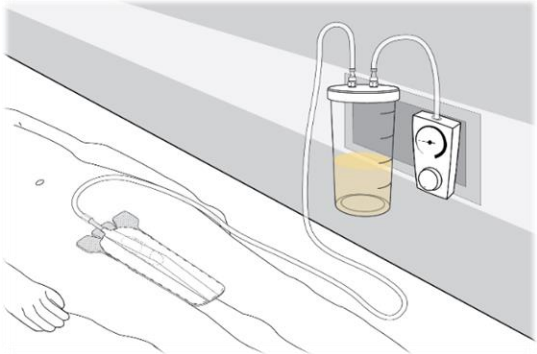
RESULT- The results indicate Qivi's novel skin friendly adhesive patch maintains skin integrity while it shows no instances of dermal irritation with repeated and extended use. The volunteers showed no signs of visual or physical impact on skin integrity. Additionally, even with minor loss of adhesion at the edges, the adhesive maintained a secure seal with extended use (24 hours) at the wrist and antecubital fossa. Under close assessment of the adhesive-patch, it was observed that volunteers with excessive body-hair had 2-3 hair follicles pulled out from the region of the application. (Note- In case of moderate to excessive pubic hair growth, trimming/clipping of follicles is recommended)

CONCLUSION- Qivi- Male External Urine Management Device adheres securely with a novel silicon-base adhesive patch. The adhesive patch conforms around a range of anatomic sizes, provides a secure seal, and maintains the microclimate at the urogenital area.

BACKGROUND- Indwelling urinary catheters (IUC's) are commonly used across the continuum of care. They may be used in the ED, in critical care, step down units, telemetry units, during surgical procedures and for the subsequent monitoring of post-operative patients. IUCs are also used for incontinent residents in alternate care facilities, such as nursing homes and in palliative care. Although only a small subset of all admitted patients, have urinary complications which require insertion of an IUC, the use of indwelling catheters has ballooned in the recent past. Sixty percent of all admissions may be catheterized over the course of their hospital stay, yet close to half (30%) of these patients do not meet the indications for the use of IUC's, while their physicians may not even be informed of their continued use. Urinary catheters may lead to complications such as CAUTI (76% of all catheterized patients), Iatrogenic Injuries (6.7/1000 patients), and hematuria. Absorbent pads and other external collectors like sheaths, condom catheters, are not designed to provide accurate output measurement of urine and have inherent shortcomings.

Qivi - Male external urine management device is a novel device that diverts urine output into a collection cannister by using negative pressure suction. Qivi mitigates the risk of UTI and traumatic injuries and can be used to achieve accurate urinary output, since there is no volume loss in the pouch or outlet tube.

METHOD- An in-vitro simulation was conducted for comparative analysis of urinary output diverted by Qivi and Indwelling Urinary Catheters in a defined period of time. The test was conducted using a silicone anatomy model while maintaining consistent output flow rate (15 ml/sec), volume (400ml) and recommended pressure for suction (40mmHg) in a controlled environment. After the allotted time, the amount of liquid inside the suction tube or inside the indwelling catheter was documented in the 'Output Retained' category. The experiment was conducted multiple times for both arms, to account for any user induced variation, and average output was recorded. Minor to no peripheral leakage was observed during any of the tests.



Device	% Volume Retention	% Volume Diverted	Time elapsed In 1 cycle
Qivi Male Ext Urine Management	0.50	99.60	90 sec
Indwelling Urinary Catheter	0.01	99.99	176 sec

RESULT – Qivi Male External Urine Management System was able to divert 99.60% (400 ml) in 90 seconds while the Indwelling Urinary Catheter diverted 99.99% urine output through the anatomy model. The Qivi device has a proprietary flow enhancing surface, which helped the Qivi device divert the fluid 48% faster than the indwelling urinary catheter.

CONCLUSION- Qivi is designed to divert male urinary output into a collection cannister using negative pressure suction. It minimizes the complications caused by other types of urine management systems like Pads, Indwelling and External Catheters while providing accurate urinary output measurements for essential clinical needs.

BACKGROUND- Wound dressings and devices routinely use an adhesive patch to secure in place at the interface of adhesive and skin. Frequent adhesive patch changes may be associated with epidermal abrasions due to the composition of the adhesives and the technique of application and may result in inflammation of the skin and clinical complications. The presence of hair follicles also affects secure adhesion and cause discomfort for patients.

Qivi-Male External Urine Management Device is designed with a silicon-based adhesive that helps secure a tight seal between the skin and the adhesive patch, while maintaining skin integrity during repeated application and removal.

METHOD- Ten Volunteers (5 male and 5 females) with diverse follicle density and sebum levels were chosen to test pain sensation upon removal of three different adhesives (marked A,B and C). Adhesive A - a Band-aid commonly used on acute care wounds, Adhesive B – Hydrogel commonly used in exudating wounds and Adhesive C - Qivi's customized silicone based adhesives were examined in the study. After cleaning the forearm with an alcohol wipe, 2 samples of each Adhesive type sized 6 x6 cm were uniformly applied. The patches were rolled with a 1KG roller to create consistent adhesion for each use-case and kept on for 10 minutes after application. The patches were then removed using a Universal Testing Machine (tensometer) to create consistent removal force and the pain associated with removal of patch was recorded on a scale of 1-5 with 5 being the most painful. Each adhesive type was removed in two different ways – In the direction of hair growth and against the direction of hair growth.



RESULT- Based on the feedback by the 10 volunteers on the pain scale, it was observed that the average score for band-aid was 3.7, for Hydrogel was 0.4 and for Qivi's novel silicone based adhesive was 0.8. The results associated with higher levels of discomfort were observed when the adhesive patches were removed against the direction of hair growth. **In the second round of testing, when the adhesive was pulled in the direction of hair growth, the results improved by more than 50% demonstrating there is low levels of discomfort and only minimal sensitivity that the volunteers felt.** Minor redness, that disappeared on finger pressure, was observed in 3 out of 10 volunteers for band-aids as compared to 0% for Qivi. In case of volunteers with excessive/dense hair, minor hair follicles (2-3) protuded out in 3 out of 10 volunteers with band-aids and in 1 out of the 10 volunteer with Qivi adhesives. Removal of bandaids is linked to perceived discomfort held in memory and often leads to anxiety among the users. None of the volunteers complained of discomfort or provided any negative feedback, while the Qivi device was removed in either direction.

CONCLUSION- Qivi External Male Urine Management device uses a skin friendly, silicon-based adhesive, which is easy to apply and remove around the supra-pubic anatomy. Presence of high amount of hair follicles prevents the adhesive from abutting directly against the epidermis, and may cause some discomfort if removed against the direction of hair growth. If a tight seal is needed for a desired clinical outcome, it is advisable to trim hair follicles prior to device application.