User Assessment of a New Pouching System Designed to Improve Discretion and Confidence

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Introduction:

There is considerable evidence that discretion of an ostomy 1 Piece Closed pouching system is an important consideration for the comfort and quality of life of a person with an ostomy. A new pouching Compared to the pouch you normally Did the flange lift from the skin? system has been developed to address this specific need, and use, the wear time of this pouch was: thereby improve their self-confidence and quality of life.

The novel design incorporates a reduced headspace, offset starter hole in the barrier, improved filter and improved closure system in drainable version. When engaged, the closure system provides a profile similar to that of the closed pouch. While providing these improvements, it is critical that the basic function of the pouching system not be compromised. The discretion and confidence benefits are addressed in a companion presentation. The assessment of core attributes is reported here.

Methods

This study was a prospective, unblinded, historically controlled observational study of a one-piece pouch with enrolment targeted to complete with a minimum of 140 subjects (70 evaluating open pouches and 70 evaluating closed pouches). The study received a waiver of review by the NHS REC and was conducted in accordance with basic ethical principles including informed consent and respect for the confidentiality of participants. Each participant satisfied the inclusion and exclusion criteria and provided signed informed consent prior to enrolment. Individual participation was for one week or upon using either 15 closed pouches or 8 open pouches m^{o} m^{o} which ever came first. Participants were asked to complete a usage diary for each pouch worn.



use, the ballooning with this pouch was: you normally use, the filter on this pouch performed:









Did you experience any leakage whilst wearing this pouch?



use, this pouch was more comfortable: use, this pouch was less noticeable



Compared to the pouch you normally Compared to the pouch you normally Did the flange lift from the skin? use, the pancaking with this pouch was: use, the wear time of this pouch was:



under your clothing:



1 Piece Open



use, the ballooning with this pouch was: you normally use, the filter on this





Did you experience any leakage whilst wearing this pouch?





use, this pouch was more comfortable: use, this pouch was less noticeable





pouch performed:



Conclusion:

Compared to the pouch you normally use, the pancaking with this pouch was:



under your clothing:

The new pouches were well accepted with approximately 85% or greater of the wear occasions being rated as being neutral or positive for the attributes such as cutting/application, wear time, security, ease of draining, filter performance and comfort. With the additional benefit of improved discretion, the new pouch should improve self-confidence and quality of life of those with ostomies while continuing to satisfy the core attributes.

The pouches in this Clinical Study are Dansac NovaLife 1 Closed and Drainabl[,] St. George's Hospital, London, UK Hillingdon Hospital, Uxbridge, UK King's Mills Hospital, Sutton-in-Ashfield, UK Jane Cox Jackie Hatton Helen Burke The Leeds General Infirmary, Leeds, UK Julie Hemmingway Lucy Ackerman The John Radcliffe Hospital, Oxford, Uk Jo Pragnell Fran Woodhouse Milton Keynes General Hospital, Milton Kevnes, L Castle Hill Hospital, Hull, UK Ann Edwards Chris Brown

