INTRODUCING **The Vyve Vue** LARYNGOSCOPE

Abstract

With its breakthrough and innovative design, the Vyve Vue improves patient safety, streamlines regulatory compliance, promotes environmental responsibility and reduces operating room costs. The Vyve Vue's patented design employs a wireless external power source paired with a one-piece integral handle and blade, thereby establishing the Vyve Vue as the first and only reusable intubating laryngoscope that can effectively achieve trouble-free, efficient and low-cost sterilization (STZ) by steam autoclave. Eliminating the batteries is the key to its simplified reprocessing. Risk of Healthcare Acquired Infections (HAI) due to cross-contamination is eliminated, instant comprehensive regulatory compliance is achieved, and a practical alternative to single use devices is realized. All, while yielding an overall 50% cost reduction.

Introduction

A laryngoscope is a medical instrument routinely used to insert a breathing tube (intubation) in a person's trachea (windpipe) in surgery. There are approximately 20-30M intubations per year in the United States; >100M worldwide.[1-3] Most laryngoscopes have two components: a handle, and a blade that attaches to the handle. After its proper positioning within the mouth and throat, a built-in source of illumination allows visualization of the trachea for intubation. Until the relatively

recent introduction of disposables, all laryngoscopes were reusable instruments and were cleaned between patient uses by rinsing with tap water or wiping with anti-bacterial towelettes (low-level disinfection – LLD) which was considered adequate.[4]

Beginning in the 1990's, due to ineffective cleaning, the laryngoscope was gradually recognized as a source of blood and bacterial contamination between patients resulting in infectious and sometimes deadly complications.[4-10] Confirmations of contamination continued into the 2000's.[11-16] These Healthcare Acquired Infections (HAI) prompted the Center for Disease Control and Prevention (CDC) to require the blade portion of the reusable laryngoscope to undergo high level disinfection (HLD) or sterilization (STZ) between patient uses beginning in 2003.[17] Design changes were necessary in order for the blade to undergo sterilization (STZ) efficiently by steam autoclave - the most economical, reliable and effective STZ process.[18,19] As a direct result, the handle gained complexity and the blade fiber optic component degraded rapidly, significantly reducing illumination during use.[20] Unfortunately, in 2003, the CDC did not apply new classification or reprocessing recommendations for the laryngoscope handle component concurrently with the blade.

This lack of handle recommendation created uncertainty within facilities regarding the 2003 CDC requirements and its oversight by their enforcement agency, The Joint Commission (TJC). This confusion then prompted the CDC to issue a clarification of laryngoscope classification for reprocessing in 2013 that again required blade components to undergo HLD or STZ, but recommended the handle be simply

processed by following the manufacturers' instructions for use (IFU). This resolution has been heavily criticized as it effectively allows facilities, without using empirical evidence, to determine the infectious risks of the laryngoscope and therefore the method of reprocessing (LLD vs. HLD or STZ).[22] The reasoning behind the CDC's open-ended recommendation is a matter of debate although many believe it is primarily because STZ of the complex handle imposed both excessive labor and replacement costs with additional unreliability of the instrument. Therefore, reducing HAI risk with STZ of both blade and handle actually *increased* overall risks with failed intubations due to malfunctions, a potentially deadly complication, in spite of the additional effort and costs involved. In addition, due to necessary reassembly and testing of components, sterility is destroyed, exposing the laryngoscope to contamination in storage, the anesthesia work environment (AWE) and at point of use, regardless of the STZ process. Hence, with limited options, many facilities today continue the ineffective practice of handle low level disinfection (LLD) per Instructions for use (IFU's). Environmental advocates support LLD of reusable handles to avoid wasting STZ resources or choosing single use disposable (SUD) laryngoscopes.[22] Many facilities have abandoned reusable laryngoscopes for SUD's exclusively. SUD laryngoscopes account for approximately 50% of intubations in the U.S., creating an estimated 3-3.5M pounds of infectious waste containing millions of batteries and costing U.S. operating rooms (OR's) approximately $2M in trash collection yearly.

In spite of this 2013 clarification, substantial reusable laryngoscope handle

contamination continues to be well documented with empirical evidence. In fact, LLD treated and 'ready to use' reusable laryngoscope handles have been determined to be the second most bio-contaminated surface in the operating room (OR); second only to the floor, and with bio-contamination levels comparable to "hospital toilet seats".[23] In addition, the bio-contamination level of the anesthesia work environment (AWE) has now been positively correlated with an increase incidence of post-operative surgical site infections.[24] Increased awareness of this connection has put AWE cleanliness under great scrutiny, with ongoing efforts to reduce the risks of cross-contamination as a source of HAI's to patients.[25] Ironically, the main instrument within the AWE, the laryngoscope, having been *proven as* a source of HAI and death from cross-contamination infections, has maintained its infectious risks while facilities hastily try disinfecting around it. A recent recommendation of the Society for Healthcare Epidemiology of America (SHEA) in 2018 was to STZ both blade and handle of the reusable laryngoscope between uses.[26] While all anesthesiology related professional organizations endorsed it, the reality of following through has proven to be effectively impossible due to current reusable laryngoscope design limitations.

<u>The Problem</u>

Reusable laryngoscope contamination with blood and pathogens, some antibiotic resistant, is, and has been, a continued threat to patients since the laryngoscopes' inception.[16] Healthcare Acquired Infections (HAI's) cost the U.S. more than $45B per year, and many professional medical related groups have made combating HAI's a focal point with initiatives to educate and improve existing LLD decontamination

techniques.[27,28] Regrettably, laryngoscope handles were designed and engineered around a power source (batteries) and not designed to be HLD or STZ. No amount of education will change that fact. When current laryngoscope blades are steam autoclave STZ (as required), the effective light intensity seriously declines over a short timeframe due to damage of the fiber optics.[20] When reusable handles are autoclave STZ, they require much time and costly labor for dis/re-assembly and the moisture causes corrosion. The resulting deterioration further exacerbates inadequate illumination levels of the blade with inconsistency and additional costs to replace instruments for premature failure or lost parts. Poor and inconsistent illumination places patients at risk of procedure failure and critical complications or death. Generally, facility risk management reluctantly accepted invisible handle contamination in lieu of maintaining presumed safety with instrument reliability. The improvement of disposable SUD laryngoscopes and their availability provided an alternative to the contaminated or unreliable reusable laryngoscope, but adopting exclusive use of SUD laryngoscopes only trades these infectious and illumination failure risks for high costs, lower quality, supply chain dependency and thousands of tons of infectious medical waste into our environment.

The Solution

Freeing the reusable laryngoscope of batteries profoundly changes laryngoscope design restrictions. The patented design, using wireless energy transfer in place of batteries, and an illumination source that can withstand STZ in place of fiber optics, transforms the reusable laryngoscope into a device capable of autoclave STZ through

a pre-existing in-facility process without dis/reassembly. An integrated handle and blade design also simplifies the cleaning and STZ process. Close to 100% of current facilities have this central processing service already in place with a professional team using economical and proven autoclave STZ to re-process thousands of surgical instruments every day. This markedly lowers costs, saves time and eliminates personnel requirements as the Vyve Vue falls seamlessly into existing policies and procedures with no additional education or training of staff. After sterilization, the Vyve Vue can be returned to the OR from central reprocessing with sterility protection so that it remains free from threats of contamination in storage until its next use.[21] This is a Joint Commission (TJC) standard that current reusable laryngoscopes cannot meet due to necessary reassembly and testing after reprocessing, whereas the illumination of the Vyve Vue can be tested without removing it from its sterile package. No other laryngoscope can accomplish this safety check and remain 100% sterile and safe.

The Vyve Vue laryngoscope will be available in direct vision (Vyve Vue DL - directly looking in the throat) or video assisted (Vyve Vue VL). Video assisted laryngoscopes for intubation have become widely available and have improved intubation success. Unfortunately, no video assisted laryngoscope in the market will tolerate steam autoclave STZ and they are also difficult or impossible to reprocess with HLD. Some video laryngoscopes have made attempts to blend reusable electronic components with disposable components, but cross-contamination risk from the reused unsterile components and the anesthesia work environment (AWE) remain. Additionally,

current recommendations of The Joint Commission (TJC) require HLD or STZ of laryngoscope components regardless of disposable protection sleeves due to unreliability. While some advocate for video laryngoscopy as a standard of care, this is currently in debate as high costs (up to 10-20 fold comparatively) have made them much less accessible and prohibitively expensive for exclusive use in uncomplicated and routine intubations for surgery. This debate can be resolved when the Vyve Vue VL video assisted laryngoscope can be steam autoclave STZ unlike any current video laryngoscope available today.

The Vyve Vue is truly unique in its usability and simplified reprocessing; advantages previously unavailable in the laryngoscope market. This is an important element of the Vyve Vue as The Joint Commission (TJC) has recently offered healthcare facilities the distinction of achieving 'Sustainable Healthcare Certification' and future financial incentives to encourage more efficient and environmentally friendly facility operations–including reduction of infectious waste. Therefore, the Vyve Vue offers facilities the opportunity to advance current trends toward healthcare environmental stewardship in a worldwide push to reduce the hundreds of millions of tons of infectious medical waste produced every year. Saving facilities roughly 50% per intubation, along with easily achieved and retained sterility within existing facility procedures and capability, is a winning long-term plan for patients, facilities, providers and the environment alike.