HALYARD

HALYARD ELASTOMERIC PUMP

TECHNICAL BULLETIN

Soft Shell Elastomeric Pump

The Halyard Elastomeric pump incorporates a soft-shell design that offers numerous advantages to the caregiver and Patient such as compact size, portability, decreased storage space and ease of disposal. This design has been on the market since 1993 with tens of millions of pumps sold. Despite the advantages of the soft shell there may be a concern that a soft-shell design is not as durable when compared to other pumps incorporating a rigid outer shell. This technical bulletin summarizes testing performed on the pump to demonstrate the integrity of the soft shell elastomeric pump.

International Standard for non-electrically driven portable infusion devices, ISO 28620:2010

The Elastomeric pump has been repeatedly verified to comply with the requirements of this standard. These requirements include durability testing of the device such as drop testing multiple times onto a hard surface, verifying proper pump functionality after application of compressive force to the reservoir and tensile force to the entire device.

Soft-Shell vs. Hard-Shell Reservoir Compression Test

To demonstrate the robustness of the Elastomeric pump soft-shell design, the Elastomeric pump, (100 ml), and a leading hard-shell competitive pump, (100 ml), were compressed until point of failure. The Elastomeric pump reached an average of 506 lbs (230 kg) before leakage occurred at the "O"-rings (note that the elastomeric layers did not burst). The hard-shell pump's elastomeric bladder burst at an average of 372 lbs (169 kg). This test found that the Elastomeric pump is more resistant to failure under compression than the hard-shell pump, even though the Elastomeric pump incorporates a soft-shell design while the hard-shell pump has a rigid outer shell.

Elastomeric Pump - Durability Testing Under Extreme Conditions

The pumps were subjected to the following testing to determine suitability for use by United States Marine Corps:

- Pumps were carried by individuals that ran through an obstacle course and pump functionality was tested after the obstacle course was completed
- Pumps were dropped from ten, fifteen and twenty feet and pump functionality was tested after impact
- Soldiers parachuted from an airplane and dropped the pumps from a height of one hundred and fifty feet
- Pumps were immersed in saltwater during a five hundred meter swim (getting pumps wet is not recommended)
- Pumps were submerged in water during a thirty-three foot dive

Pumps survived all testing noted above intact and operable. The elastomeric pump was determined to be durable, easy to pack and carry, supported quicker venous access for fluid delivery and accomplished pressurized delivery more consistently.

Conclusion

The Elastomeric pump tests outlined above demonstrate the durability of the soft-shell design under a variety of extreme conditions.[1] At no point during any of the tests did a pump bladder burst and the pumps functioned as expected. Additionally, in a study published in the British Journal of Nursing, patient preference was assessed comparing two widely-used elastomeric infusion devices, one a soft-shell the other a hard-shell design. Eighty-three percent (83%) of participants preferred the soft-shell design primarily because of its comfort and discreetness. [2]

References

1. Data on file, Halyard Health.
2. Dodd S. Assessing patient preference for two types of elastomeric infusion device. **British Journal of Nursing** 2007;16 (19).

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings** and **Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to www.halyardhealth.com for additional product safety **Technical Bulletins**.

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