Spray Applicator

Usability evaluation for safe and effective device use

BACKGROUND AND CHALLENGE

A spray applicator is a medical device used by nurses and surgeons to spray a sealant in sites inaccessible to "surgical" when controlling the bleeding by conventional surgical techniques is ineffective or impractical.

Tata Elxsi took up the challenge to do a Usability Evaluation of the device for safe and effective use.

SCOPE OF WORK

- Assess the performance of nurses carrying out tasks that are critical to the safe and effective use of the device

- Identify usability issues that affect user performance and satisfaction

- Evaluate usability requirements and the effectiveness of risk control measures to minimize or prevent the occurrence of use errors

- Obtain users' ratings on device handling, the IFU, and training

- Document any changes recommended by participants

- Identify aspects of the UI that users like the most and the least

A LEADING MEDICAL DEVICE MANUFACTURER

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SOLUTION

- Tata Elxsi team did the Use Risk Analysis to assess all the tasks for every user population to determine where a use-related error could lead to a hazard / hazardous situation ending in harm. This Use Risk Analysis helped to determine critical task performance criteria to be used in both Formative (Verification) and Summative (Validation) testing. Formative Evaluation was done to validate the design and development of the device and user interface.

- An iterative Formative Evaluation process was followed to inform design decisions and assess all critical tasks with users ahead of the Summative Evaluation. The process was followed complying to IEC62366-1.

IMPACT

- The formative evaluation testing done by Tata Elxsi led to design refinements resulting in very low-risk ratings.

- This evaluation document was a critical input to the Usability Engineering File, which forms part of the overall device's Design History File (DHF) required for submission to the regulatory authorities.