



# Packaging system challenge in France: test of a new nonwoven pack.

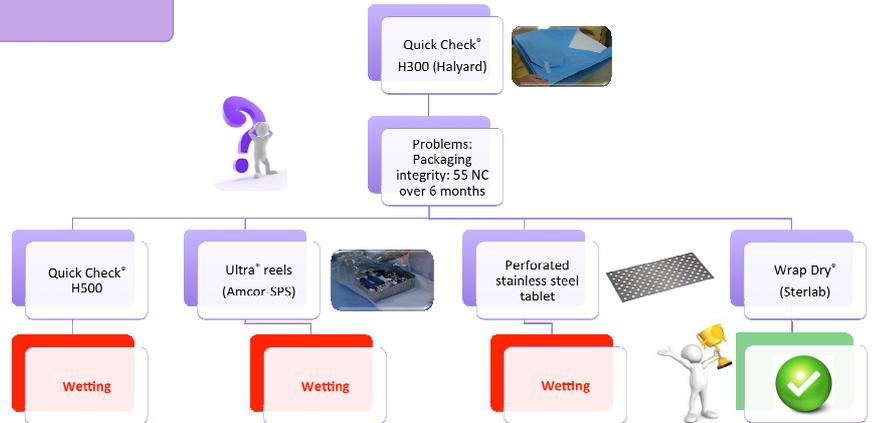
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## Introduction

The Central sterile supply department (CSSD) has had several reporting of adverse events due to non-compliance (NC) of wrapping packaging. The operating room (OR) met problems of packaging integrity (damaged, holed). The main problem of CSSD is the residual condensation inside pack. The sterility could be compromised and the pack must be processed again. Patient's management could be delayed.

Sterilization cycle was optimized for our loads, so to improve customer satisfaction and to respect quality approach ISO 9001:2008, CSSD has tested different wrapping package (stronger sheet, Ultra  , perforated stainless steel tablet). All were inclusive and purchasing additional containers represented a too expensive budget for our hospital.

Finally, the CSSD chose to test a new protective packaging Wrap Dry   (STERLAB), just marketed in France.



## Material & Method



Figure 1 : WRAP DRY   wrapping



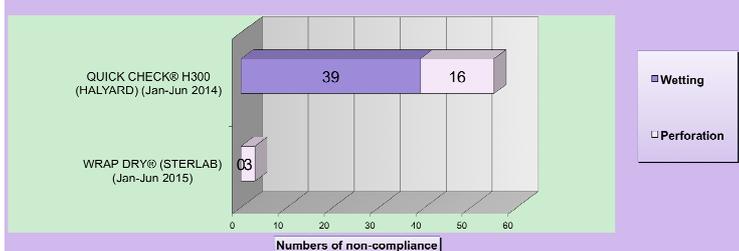
Figure 2 : WRAP DRY   packaging

We tested WRAP DRY  : a violet nonwoven sheet developed to package heavy medical devices. The sheet is constituted by an exclusive material resistant polypropylene and combined to a hydrophilic layer. This packaging system (PS) is compared to QUICK CHECK  : 2 sheets in nonwoven bonded together and made of polypropylene usually used.

Tests carried out for the annual autoclaves operational qualification. To respect the standards ISO 11607-1 and EN868-2, the packaging system is wrapping of 2 layers: a blue paper (Sterile Barrier System) and WRAP DRY   (barrier and protection). A satisfaction survey adapted to sterilization technician and operating room nurses/surgeons was conducted after use. We extracted the sterilization software's data to compare NC over the first six months of use with one equivalent activity period.

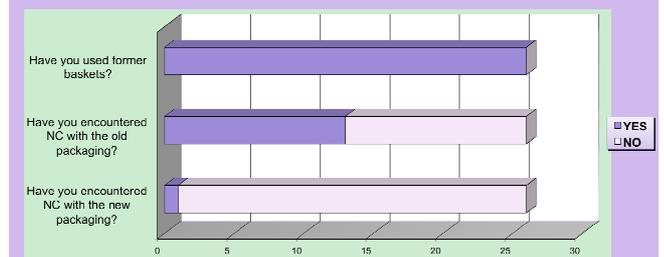
## Results

### Internal non-compliance over 6 months



With the old PS, CSSD raised 55 internal non-compliance: 39 NC of "wetting" 16 NC of "perforation".  
Over 6 months, with WRAP DRY  , we raised 3 NC of "perforation".

### Non-compliance survey OR/Surgeons



26 OR nurses/surgeons answered the investigation: 50% met NC of "perforation" with QUICK CHECK  



Global satisfaction shows that 65% of users are very satisfied of the WRAP DRY   packaging.

- ✓The sterilization technician find the folding time longer (+ 100%) but they do not considered it like a negative point. Thanks to the resistance, less packages have to reprocess.
- ✓Operating room staff are satisfied of the technical characteristics of the product (safety, storage).

## Discussion - Conclusion

Significant decrease of the non-compliance makes acceptable the increase folding time by the sterilization technician. Conservation of a packaging with two colours allows visualising any defect.

New packs were tested during the annual autoclaves requalification period to optimize the sterilisation cycle.

For the same packaging size, the cost is not more expensive. The packaging with SBS and TWRAPDRY costs 0.0349   higher.

After 2 years of test, we find the PS which corresponds to our activity.

Results of satisfaction survey confirm the non-compliance figures recorded: thanks to this new packaging system, the CSSD answers operating room's waitings. This work allows to find comfort and security for the surgeons and to improve management's patients in surgical unit.

