



# Pharmaceutical Packaging: Investigation into older patient centered design

## Ease of opening - target group studies based on CEN/TS 15945

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## Content



# Pharmaceutical Packaging: Investigation into older patient centered design

- CEN/TS 15945: Normative Target Group Test
- Comparative study of aluminum-aluminum type blister vs. PVC-aluminum type blister
  - Evaluation of possible correlation of ease of opening with measured extraction forces
- Follow-up studies to define and evaluate design factors for the ease of opening of blister packaging for solid dosage forms
  - Transparency
  - Geometrical fit of dosage form
- Vitamin Supplement Drinks
  - Packaging Concepts
  - Influence of education methods



## CEN/TS 15945 – A three step test

1. Opening Effectivity
  - A test person has to open one package
    - *within 5 minutes*
2. Opening Efficiency
  - A second (identical) package must be opened
    - *within 1 minute*
3. Patient / Consumer Satisfaction
  - A portion of the product must be taken out of the second package and packaging must be reclosed (if applicable)
    - *within 5 minutes (including second opening procedure)*
  - After repeated opening procedure the users rate their satisfaction on a scale from – 2 to +2
    - *Acceptable, if satisfaction is rated with at least 0*



## Target Group Test subject to CEN/TS 15945

- Age range

Age Groups	Male %	Female %	Total %
65 - 69	10	25	35
70 - 74	10	25	35
75 - 80	10	20	30
Totals	30	70	100

- Sequential method

Number of Target Group Participants	Number of Successful Opening Procedures	Number of Failed Opening Procedures	Confidence Interval (%)
20	20	0	85 to 100
40	38	2	82 to 99
60	56	4	83 to 97
80	75	5	85 to 97
100	94	6	87 to 97



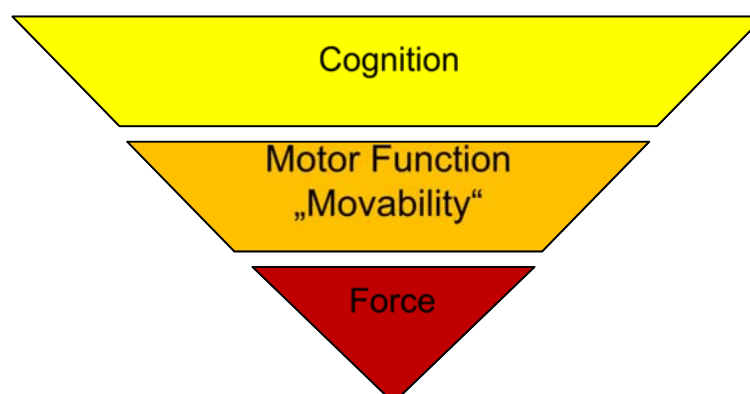
## Target Group Test subject to CEN/TS 15945

- Target Group Test Design +
  - „Kitchen-Table-Scenario“
  - Autonomous Lifestyle
  - Video analysis of hand movements
  - Detailed evaluation of packaging concept challenges

## Modelling of Opening Procedures



## Human factors for easy opening



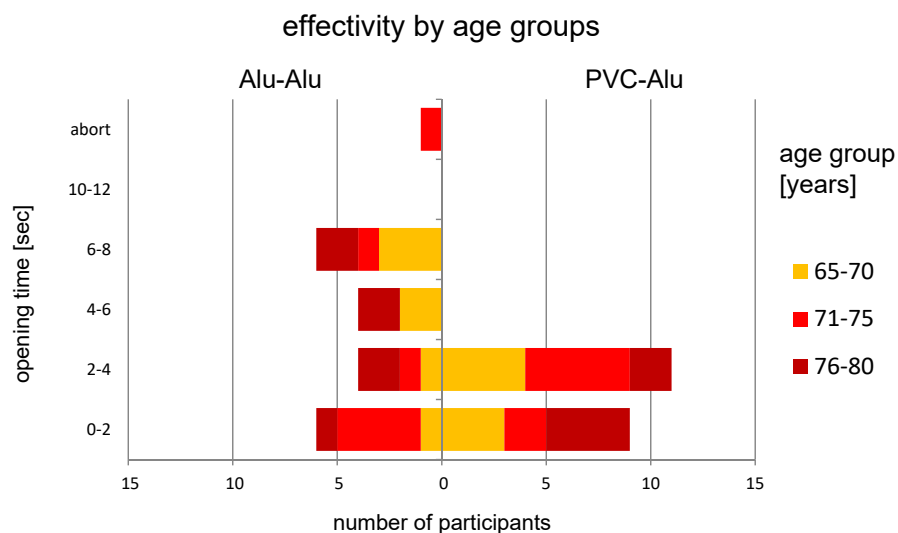
# Initial Study

- Comparative study of aluminum-aluminum type blister vs. PVC-aluminum type blister
  - Evaluation of possible correlation of ease of opening with measured extraction forces



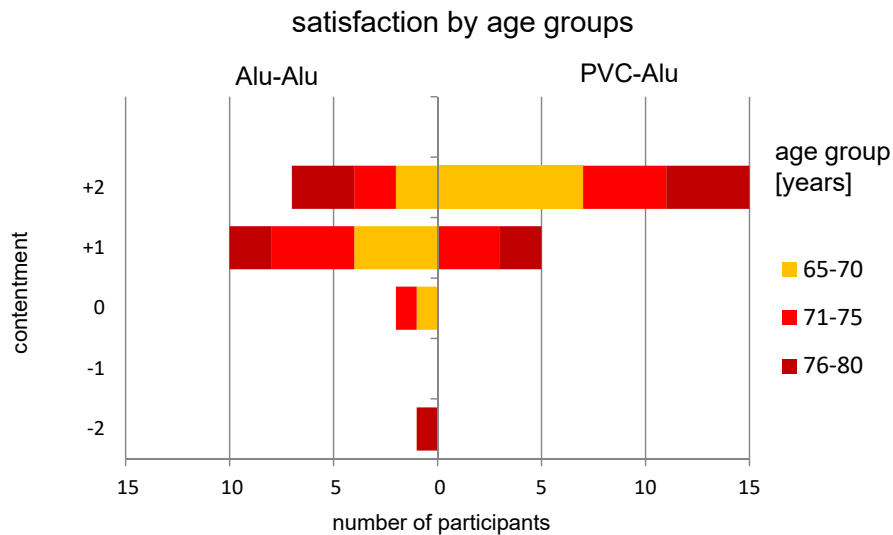
## Initial Study - Effectivity

# Time to Open Alu-Alu-Blister vs. PVC-Alu-Blister





## Patient Satisfaction Alu-Alu-Blister vs. PVC-Alu-Blister



- Lower opening forces for alu-alu blisters, however
  - increased opening time in target group study
  - reduced patient satisfaction



- Tablet in aluminium-aluminium blister has more space in the larger cavity for **coincidental movements**
- **Intransparency** of alu-alu blisters inhibits the patient to execute a specific pressure movement, as tablet's position cannot be observed

**Pressure is applied randomly!**

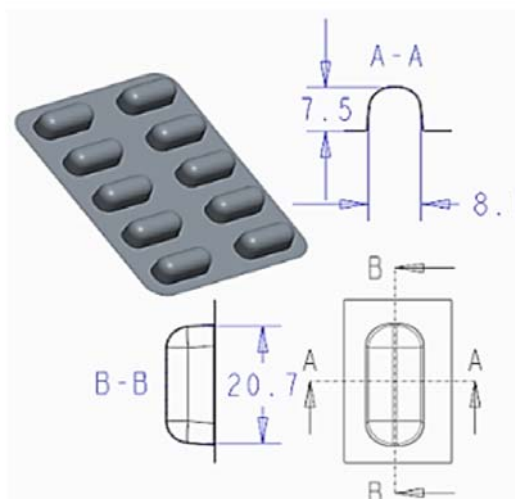
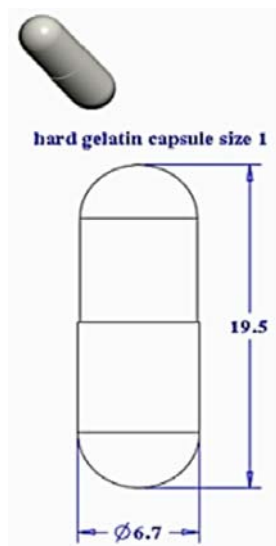


## Follow-up Studies

- Follow-up studies to define and evaluate design factors for the ease of opening of blister packaging for solid dosage forms
  - Transparency
  - Geometrical fit of dosage form

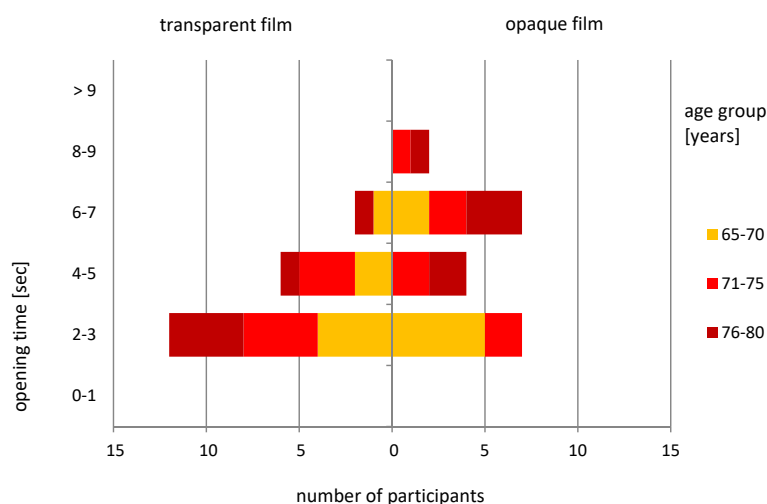


# Evaluation of Transparency



# Evaluation of Transparency

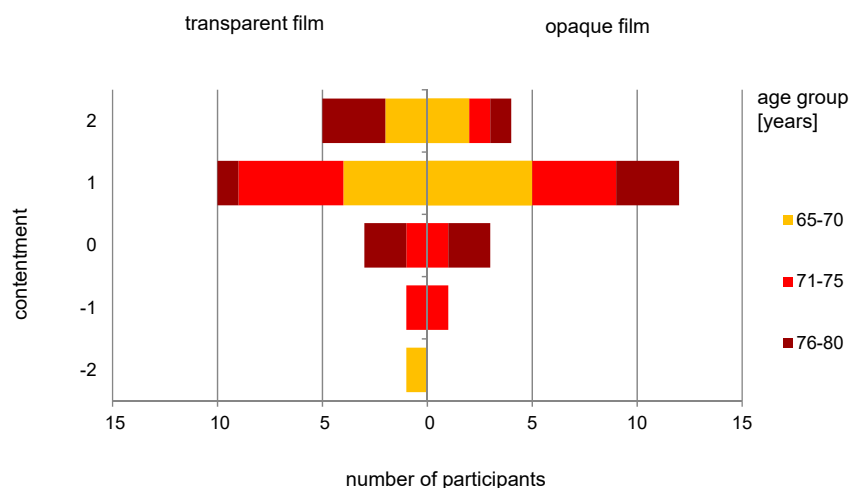
- opening time:  
opaque film vs.  
transparent film





# Evaluation of Transparency

- patient satisfaction: transparent film vs. opaque film



# Evaluation of Geometrical Fit

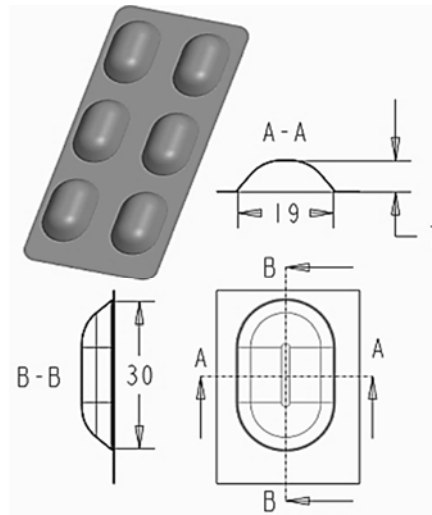
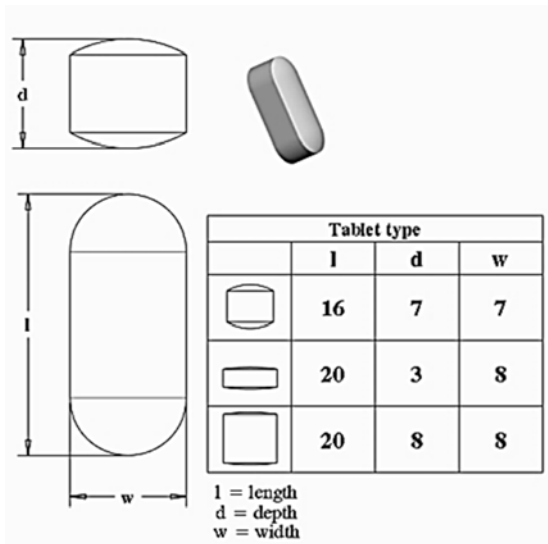


Views of studied tablet dimensions:  
20x3 mm (left), 16x7 mm (middle) 20x8 mm (right)





# Evaluation of Geometrical Fit



# Evaluation of Geometrical Fit - Tablet 16x7 mm -

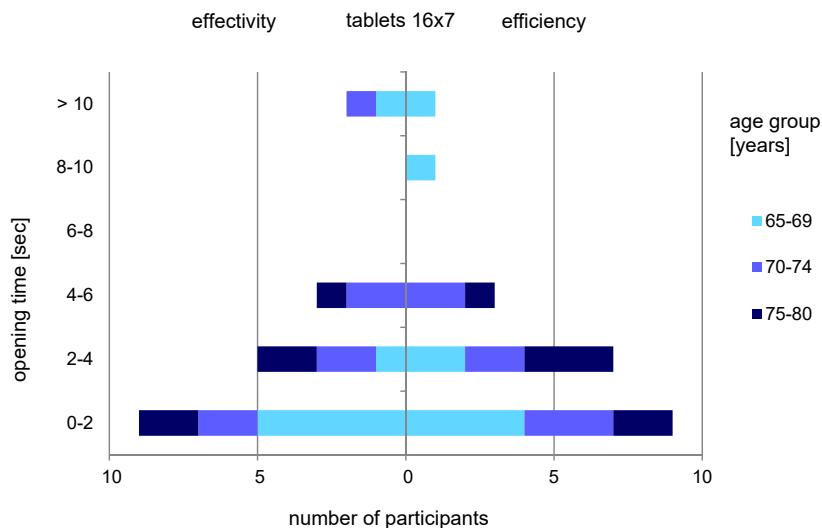


Views of tablet 16x7 mm and blister stripe



# Evaluation of Geometrical Fit - Tablet 16x7 mm -

- Median effectivity 2,69 sec
- Median efficiency 2,17 sec



# Evaluation of Geometrical Fit - Tablet 20x8 mm -

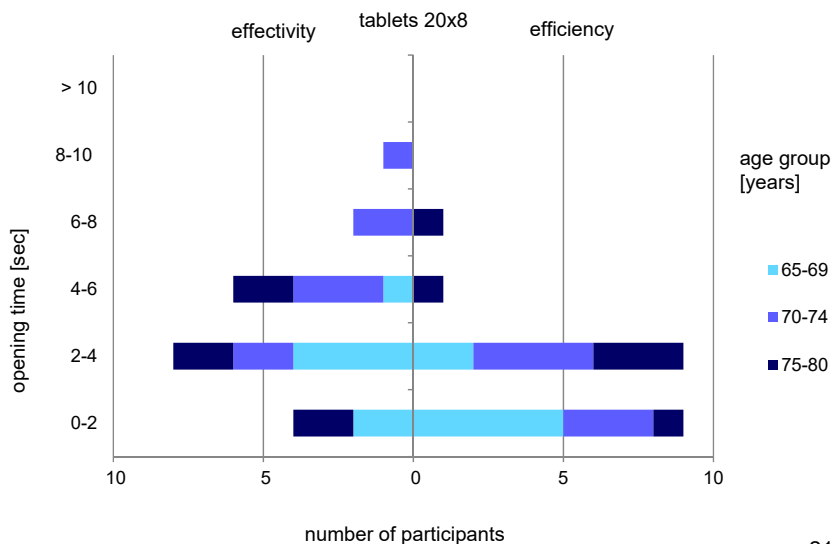


Views of tablet 20x8 mm and blister stripe



# Evaluation of Geometrical Fit - Tablet 20x8 mm -

- Median effectivity 3,42 sec
- Median efficiency 2,17 sec



# Evaluation of Geometrical Fit - Tablet 20x3 mm -

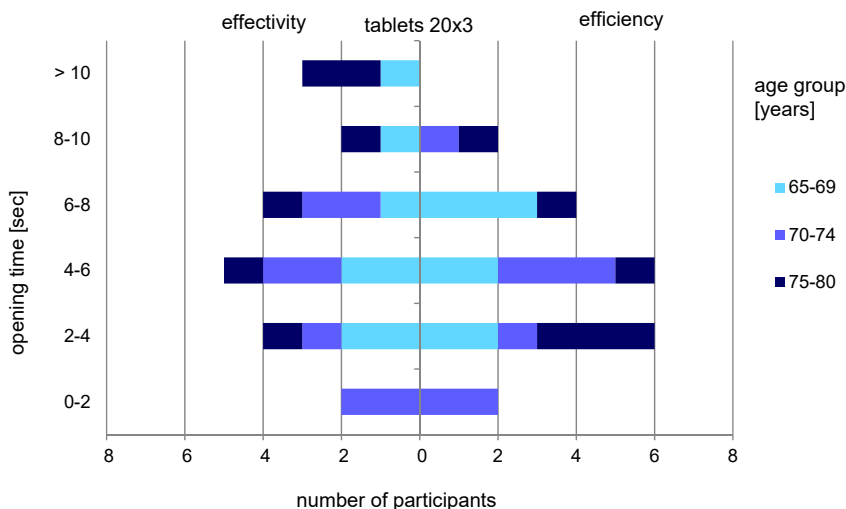


Views of tablet 20x3 mm and blister stripe



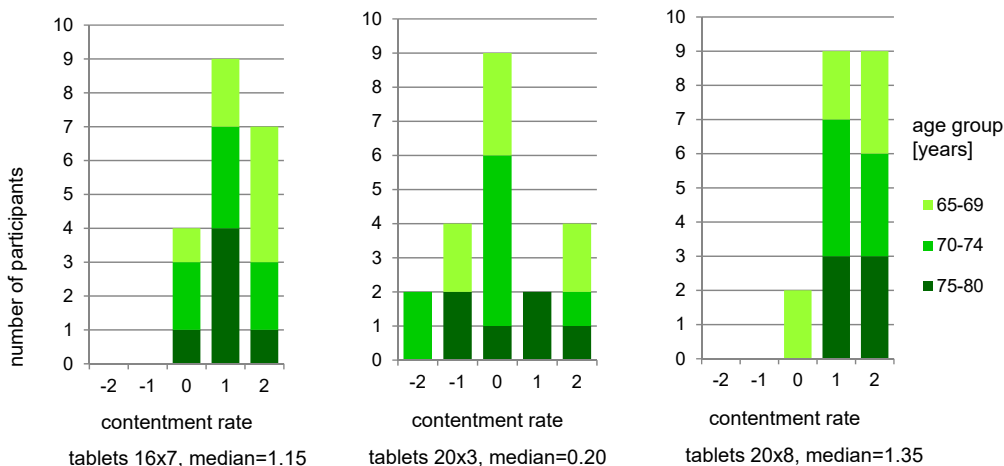
# Evaluation of Geometrical Fit - Tablet 20x3 mm -

- Median effectivity 5,09 sec
- Median efficiency 4,78 sec



# Evaluation of Geometrical Fit

- Tablets satisfaction rating





# General Design Recommendations

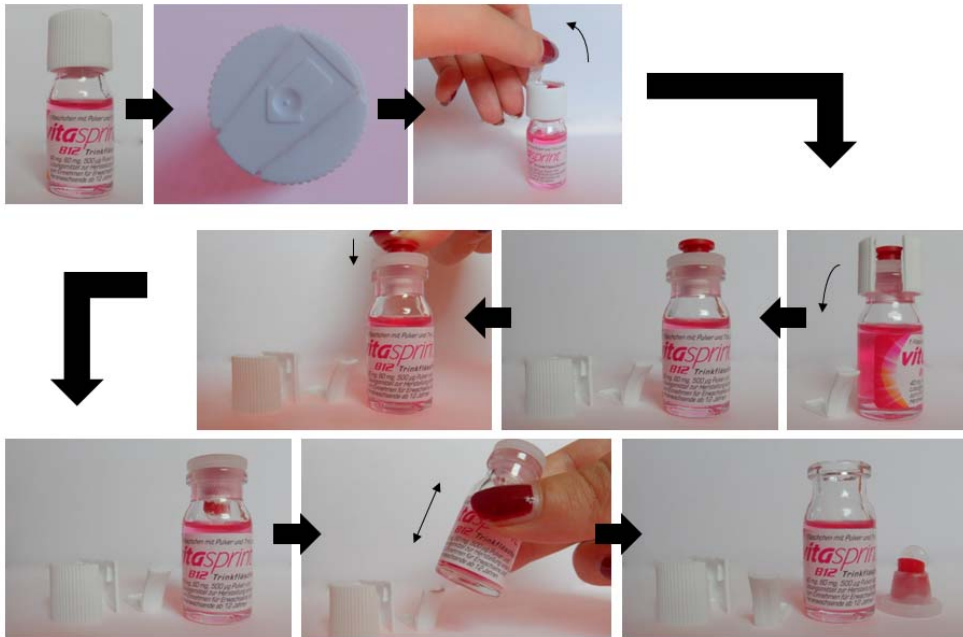
- Cavities should not be too large
- Cavity well tuned to tablet size and shape
- Rigidity of packaging material must be suitable for dosage form
- Transparent film: Visibility of tablet is helpful

**One Size does not fit all!**



# Vitamin Supplement Drinks





Opening procedure of Vitasprint™

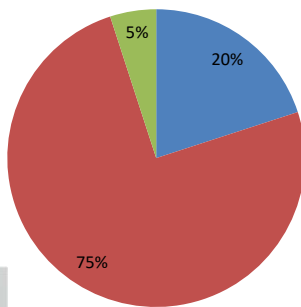


Opening procedure of Vita-Kick™



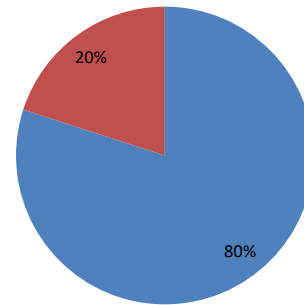
# Familiarity with Packaging Concept

Vitasprint™



Kloster Eberbach  
Nov. 17<sup>th</sup>, 2017

Vita-Kick™



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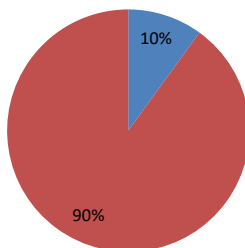
20% of participants mistake it for eye-drops or other pharmaceutical

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# Correctness of Opening Procedure

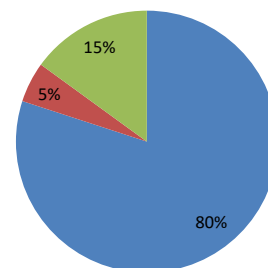
Vitasprint™



35% of participants mistake plug of powder compartment as opening aid

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Vita-Kick™



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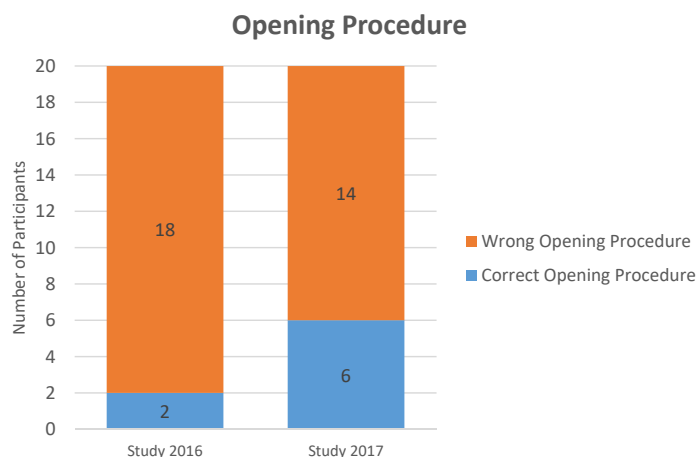


# Vitasprint™ – New Study 2017

- Perceived increased media presents with embedded opening instructions, e. g. TV spots
- Reported increased activity of sales force encouraging pharmacists to explain packaging



# Vitasprint™ – Comparison of Studies

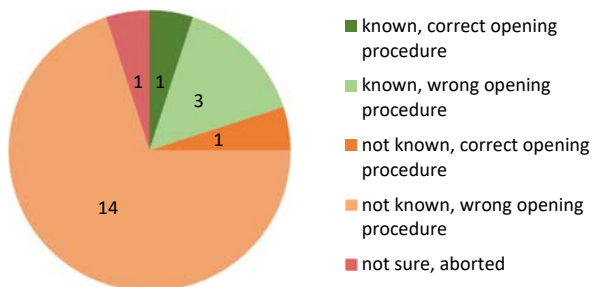






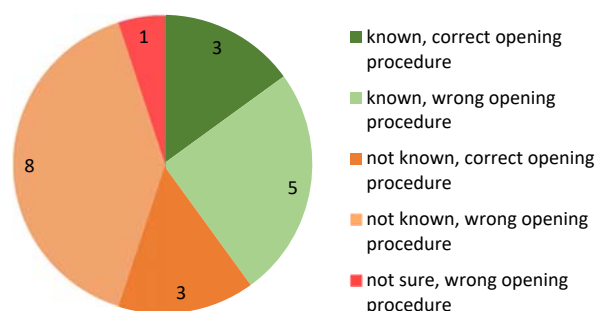
# Vitasprint™ – Comparision of Studies

Study 2016



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Study 2017

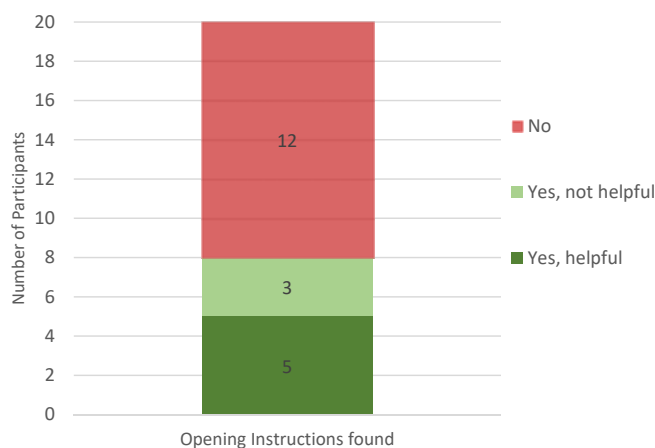


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# Vitasprint™ – Opening Instructions

Opening Instructions



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# Vitasprint™ – Comparison of Studies

## Conclusion

Complex packaging or application aids require **professional** education, instruction or assistance by **pharmacists!**

## Literature



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