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REPORT ON NEW SOLUTIONS FOR PHARMACEUTICAL PACKAGING

## **OPTIMIZING THE BREAKFORCE RANGE TOWARDS LESS COMPLAINTS AND REDUCED RISK FOR INJURIES**

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A CASE STUDY BY  
FLORENCE BUSCKE, SCHOTT AG

**SCHOTT**  
glass made of ideas



# OPTIMIZING THE BREAK- FORCE RANGE

## TOWARDS LESS COMPLAINTS AND REDUCED RISK FOR INJURIES

**G**lass ampoule is a very traditional primary packaging container for pharmaceuticals that has been successful for many years. In fact, It has been developed in the 1890's and nowadays the market for ampoules is still growing and even booming in emerging countries. Reasons are multiples, such as purity with only the glass in contact with the drug, efficiency in machinability and cost-effectiveness.

Over the time, different break systems have evolved, and surprisingly there are certain regional hot spots for each break system used in the world. Namely, there are three: Scoring, Color Break Ring and One Point Cut.

The first ampoules had no break system in the past, nurses & Health Care Professionals were using a saw to open the ampoules, then came the scoring & color Break Ring system which consist

**For scoring:** a score is applied all around the constriction of the ampoule which defines the breaking area.

Scoring is the favorite option for cosmetic application due to its non-orientation dependence (no dot).

**For Color Break Ring:** a color (enamel) ring is printed all around the constriction, a pre-scoring can be applied prior. The color ring has an higher coefficient of thermal expansion than the glass. It weakens the glass at the position,

during the annealing process, this defines the breaking area. It also has non-orientation dependence (no dot) but leads to enamel particules when the ampoules is not opened in a proper way.

For legacy reasons, Color Break Ring remains the most used break system in Latin America but tends to move toward One Point Cut due to change in the regulations of heavy metals content in the color for the ring, which has a functionality in the break force range as well.

Scoring and Color Break Ring offer the same break force range according to the ampoules format, as an example for a 1 ml ampoule the break force range defined in the ISO 9187- part 1 to open the ampoule is between 30 N to 80 N, the bigger the ampoule format, the bigger the force is required.

— For One Point Cut: a cut is applied at a precise position in the constriction, not all around, and a dot is printed above the cut as an indication for opening.

— One Point Cut break system allows a narrowed break force range due to a more precise technology, for example, a 1 ml ampoule the break force range defined in the ISO 9187 – part 2 to open the ampoule is between 25 N to 65 N. It is the most used worldwide, with Europe as the biggest concentration, then comes Asia.

An overview of all break systems and their ISO tolerances in relation to the different filling volumes can be seen in figure 1. The general break systems are compared to SCHOTT's new easyOPC break system seen in figure 1 and 2.

*A case study by  
Florence Buscke,  
SCHOTT AG*





**TOTAL AMPOULES WORLDWIDE 2019\***

24 Bn units and split by break system (% linked to the graph below in figure 2)

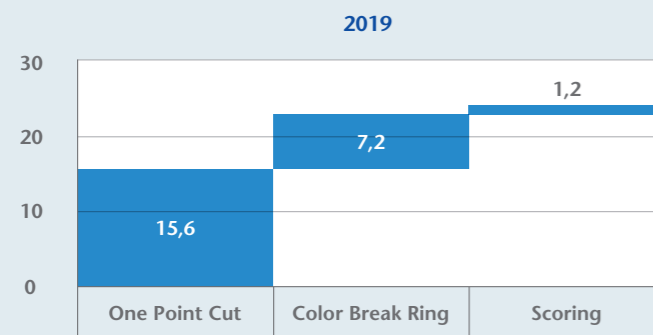
- 65% One Point Cut
- 30% Color Break Ring
- 5% Scoring

\*Internal estimation based on market feedback

	easyOPC tighter than ISO 9187-2	One Point Cut ISO 9187-2	Color Break Ring & Scoring ISO 9187-1
1 ml			
2 ml	25-45N	25-65N	30-80N
3 ml			
5 ml	30-60N	30-70N	
10 ml	30-65N*		30-90N
20 ml		30-80N	
25 ml	-		30-100N
30 ml			

\*Coming soon für easyOPC in 10 and 20 ml

**FIGURE 1:**  
Comparison of different break force ranges for different break systems and filling volumes.



**FIGURE 2:**  
Ampoules market in 2019, break systems in Bn units (linked to the % above)

**TYPICAL APPLICATIONS STILL SEE A HUGE BENEFIT IN AMPOULES**

Ampoules are the oldest primary packaging container and it is still the most used to store pharmaceutical products in this time. Glass ampoules play an important role in the wide-spread supply of basic medicine, such as pain killers, inflammation inhibitors and anesthetics.

On well-established markets they are both an affordable as well as reliable. In emerging markets, such as Eastern Europe, South America, Asia and even in Africa in future, there is a large demand for supplying basic drugs, which can be met using ampoules. China, for example, one of the markets with the highest growth, uses the very latest machines, but these are incompatible with conventional ampoules. Our SCHOTT ampoules, which are ideally suited to these machines due to their quality specifications, ensure optimum results.

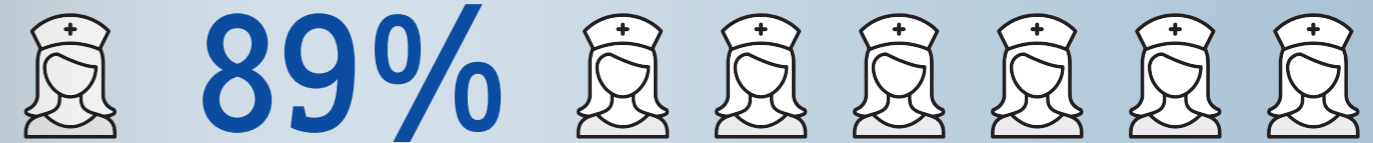
Glass has an image of purity and we also see a trend to store cosmetics preparation in a glass ampoules such as hair loss, anti-aging and skincare treatments.

**HOW CAN A TRADITIONAL PRIMARY PACKAGING BE INNOVATIVE?**

It's 1:30 in the morning. There's an emergency. The nurse reaches to open an ampoule of medicine. It shatters in the rush. The nurse gets hurt and the ampoule winds up in the trash. This is just one of many similar scenarios around the world. They cost more than nerves and valuable time, but a lot of money as well. An estimated 1 billion euros of hidden costs are incurred in this industry alone. How can you save the nursing staff, the finance department and yourself the trouble?

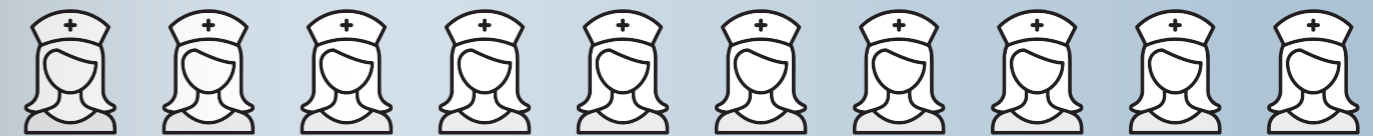
Did you know that 82 million ampoules are opened on a daily basis worldwide by 21.7 million Health Care Professionals? Health Care Professionals often need several attempts to open the ampoule. Sometimes, the ampoules do not open at all. Hard to open ampoules can lead to injuries. Such situation still happens even with the break system One Point Cut which offers already the smallest standard deviation for breakforce and the least particle generation during opening. One Point Cut has the disadvantages of orientation dependence and shows in some cases the effect, that the ampoules are almost impossible to open (hard to open ampoules). The market defect rate of AQL 0.4 (400 ppm) is not acceptable anymore. **This is definitely telling us that ISO breakforce range is too far from real market situation.**

The problem of opening ampoules impacts the entire value chain, SCHOTT went beyond and heard the voice of the experts. An anonymous survey conducted by SCHOTT among 700 nurses in Europe, in 2018. The outcomes were **tremendously astonishing: From Health Care perspective, the opening of an ampoule is the #1 root cause of injuries at hospitals.**



**89%**

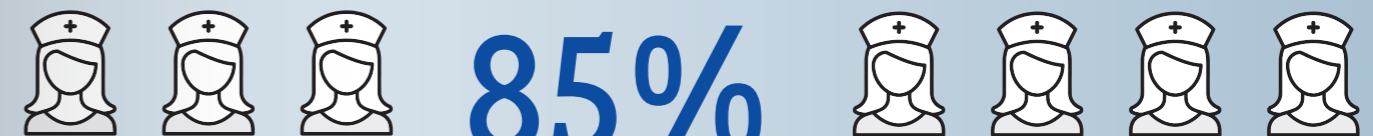
*of nurses have difficulties in opening ampoules up to 10 times a month.*



*From Health Care perspective, the opening of an ampoule is the*

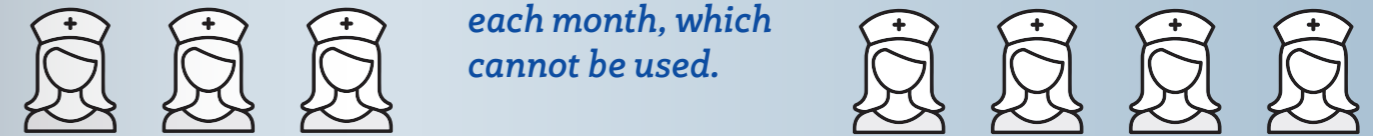
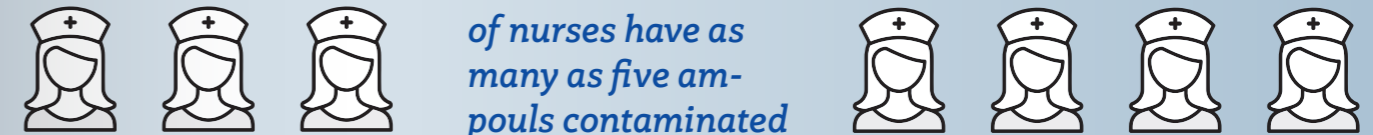


**#1** *root cause of injuries at hospitals.*



**85%**

*of nurses have as many as five ampoules contaminated with glass splinters each month, which cannot be used.*





## Unusable and unbreakable ampoules result in over one billion € waste costs every year.

A very interesting fact from the survey showed that >85% of nurses face problems with ampoule handling (unbreakable or bad breakage). By asking the range of involved ampoules which cannot be used, we came up with an average numbers of 114 unbreakable and unusable ampoules per nurse and per year when extrapolated it to an estimated total number of 10 M nurses worldwide using ampoules at hospitals ( it comes from the 21,7 M Health Care Professionals reported in the WHO).

Schott applied then an average price per ampoule of 1 € that we multiplied by the number of nurses (10 M) and the number of unbreakable/unusable ampoules per nurse per year (114). We came out with an hidden industry cost of >1 B € (waste of drugs). This calculation shows already the iceberg effect, it might probably underestimate the total cost.

**From Pharma companies perspective: we talk about a degraded profitability due to high quality costs and market reputation risk.**

Complaints from the market consume resources from quality departments. Strict incoming inspections on place increase quality work load. Complaint management generate costs of ~200 million\* EUR annually.

\*Internal calculation: extrapolated complaint rate from a specific market to the global One Point Cut ampoules market

# 22%

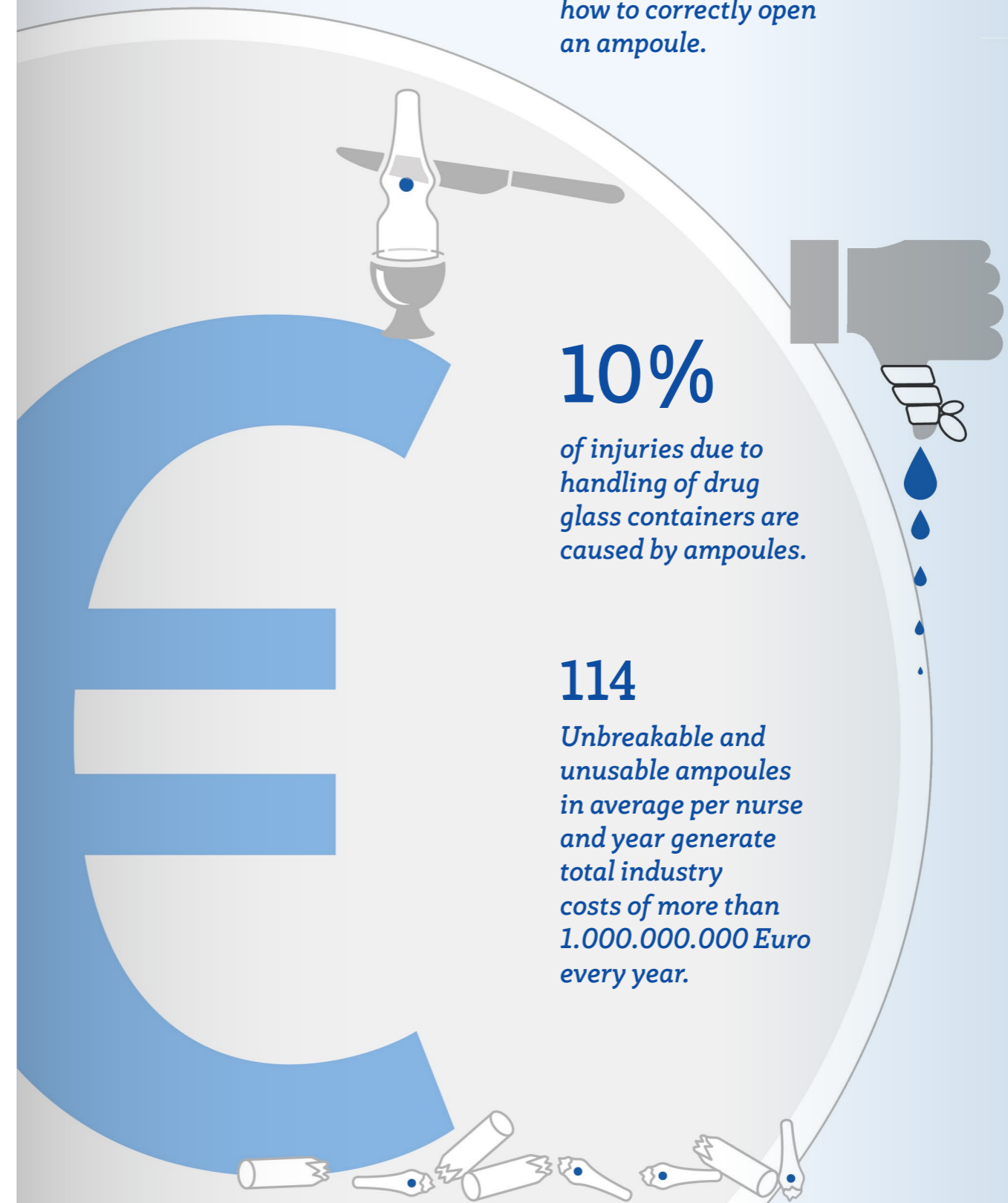
of nurses do not know how to correctly open an ampoule.

# 10%

of injuries due to handling of drug glass containers are caused by ampoules.

# 114

Unbreakable and unusable ampoules in average per nurse and year generate total industry costs of more than 1.000.000.000 Euro every year.



Breakforce measurements comparison  
One Point Cut vs. easyOPC commercial production

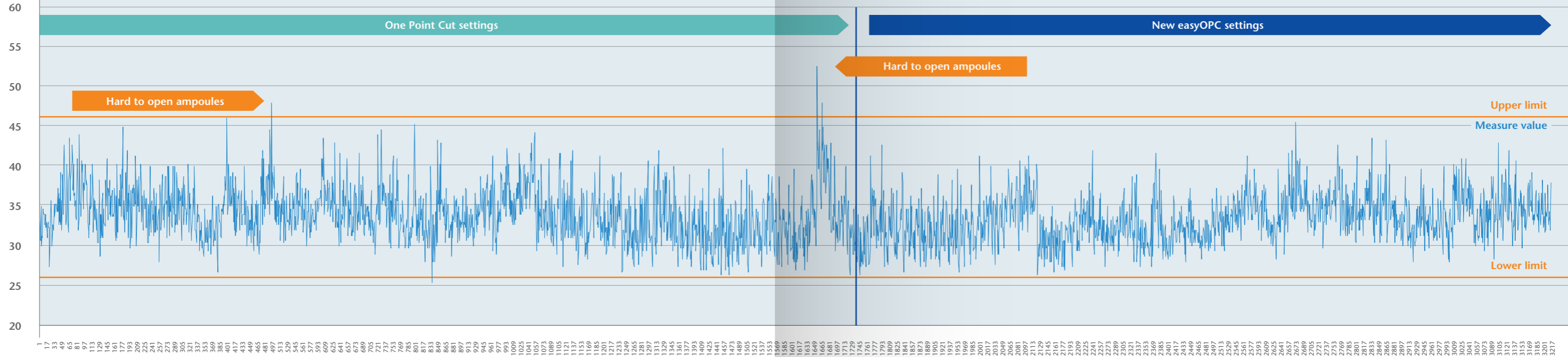


FIGURE 3:  
Reference range: 26-46 N / Ampoule 1 ml Form C

A DEPTH ROOT CAUSE INVESTIGATION TOGETHER WITH SCHOTT CUSTOMERS AND EXPERTS

To minimize the issue of hard to open ampoules, leading to frequent market complaints, a depth root cause investigation was necessary. Out of it, a new feature, the easyOPC was born.

Thanks to the feedback from market users, the more than 40 years knowledge of our glass converting, quality and technical services SCHOTT expert, we have been able to hack the behavior of glass breakage.

These findings, which are classified as company secret, have allowed us to optimize the forming of the constriction during converting and the application of the cut. These parameters lead to narrow the breakforce range.

Additionally, with a tighter quality control for breakforce range, we are able to provide a tighter specification for this cosmetic defect

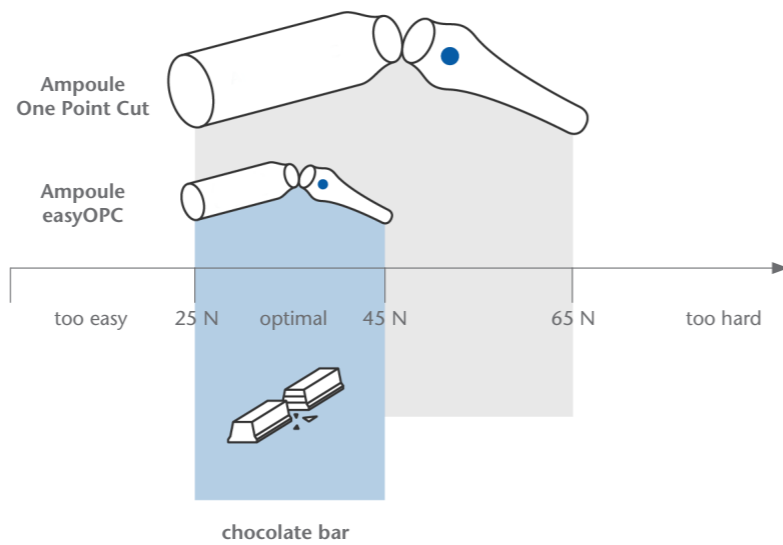


FIGURE 4:  
Graphs break force range obtained easyOPC vs. One Point Cut

from an AQL of 0.4 (400 ppm), we went down to 50 ppm in product lot (meaning 0.01 for incoming inspection)

easyOPC could be translated into this simple formula: easyOPC = Process Optimization + Tighter specifications

These optimizations have no impact on the product registration files. It decreases incoming inspection and market complaints, it results in efficient, fast and cost competitive F&F process.

Since the start of the project, we recorded a drastic drop in Out of Specs during In-Process Control and in numbers of market reactions from our customer.

easyOPC allows a safe & easy drug administration for Health Care Professionals & Patients, by coping with unmatched opening performance, reducing injuries at point of use and reducing the amount of unbreakable ampoules.

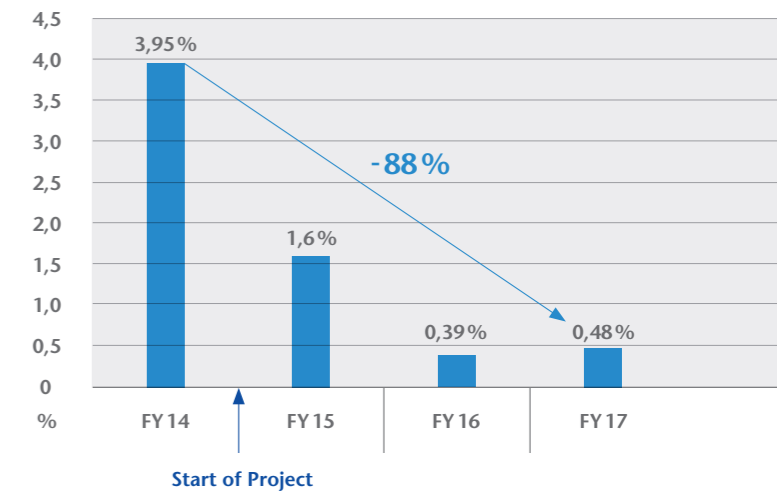


FIGURE 5:  
Number of blockings at our production site in %





### WHAT IS THE SECRET RECIPE IN OPENING AMPOULES WITHOUT INJURIES OR SPLINTERS?

The secret is a combination of two ingredients:  
 — An optimized break system such as easyOPC  
 — Training! As a supplier we must provide handling recommendations with the Do's and Don'ts to the end-users, we have the expertise on the behavior of glass breakage and we have to share it. Therefore we have released new video on the opening of One Point Cut ampoules on our SCHOTT Pharma YouTube channel: [follow this link](#).

### PROVEN TRACK RECORD

Until now, more than 30 Mio. easyOPC ampoules delivered, filled by our customers and shipped to the Japanese market. The market complaint rate has fallen drastically to 20 ppm. Today: the AQL level is at 0.4 as a standard (400 ppm). SCHOTT easyOPC has been recognized by independent juries worldwide with a final nomination at the CPhI Awards 2018.


#### Customer cases The probability Japanese market loss

##### Customer Case 1 in 2015

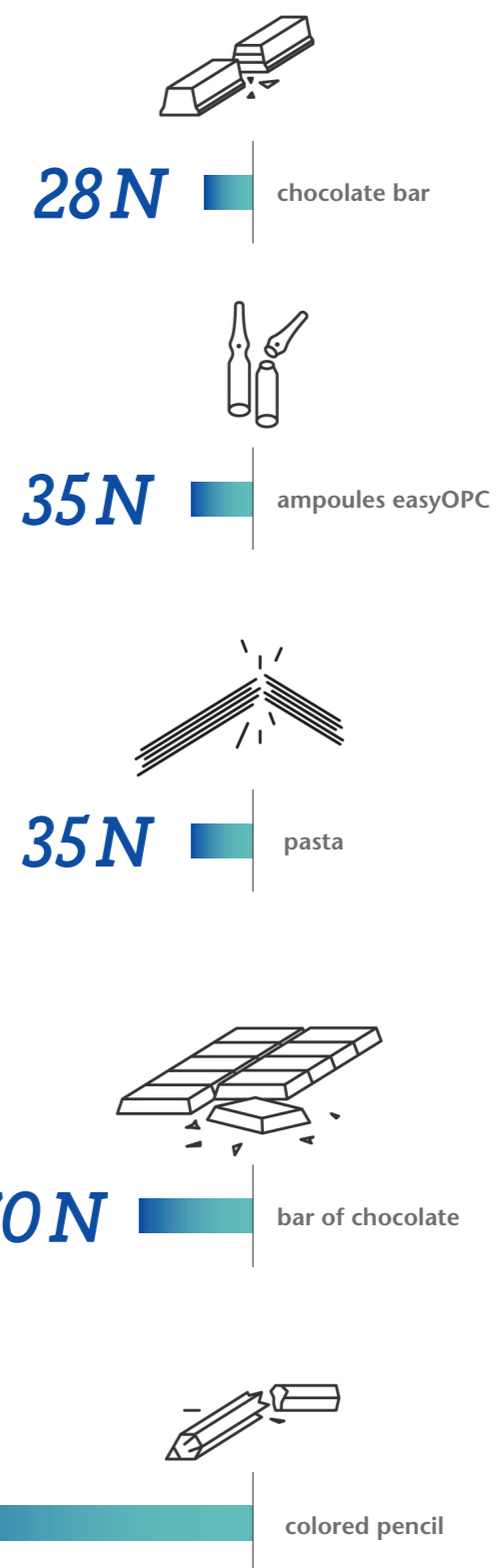
**2015:** Appearance of hard to open ampoules in Japan  
**Risk:** Loosing market due to non-acceptance.  
 Customer does not accept unbreakable or hard to open ampoules anymore.  
**Business at risk** ~ 200 mio \$ (15 mio pcs)  
**2017:** Customer switched all One Point Cut ampoules to easyOPC.

##### Customer Case 2 in 2019

**End 2019:** >1 Mio units easyOPC ampoules delivered, filled and shipped to Japanese markets.  
 Successful transition from ampoules One Point Cut to ampoules easyOPC with, up to now, a market feedback from hospitals in Japan of less (zero) complaints in terms of hard to open or not to open ampoules.

 For more information, please visit: [breakingmoments.com](http://breakingmoments.com)

What object requires a similar break force as a SCHOTT ampoule easyOPC?



**FIGURE 6:**  
Approx. values from an internal test performed by SCHOTT

# FLORENCE BUSCKE

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