

# EuCard<sup>2</sup> Workshop with Industry

## Sterilization of pharmaceutical packaging

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| December 8<sup>th</sup> and 9<sup>th</sup>, 2016, Warsaw, Poland



**METALL+PLASTIC**  
Cleanroom Technology



## Products

### GLOVE TESTING SOLUTIONS



### ISOLATORS/RABS

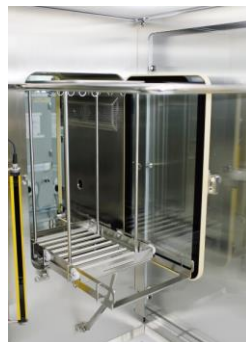


Filling isolators



Sterility testing isolators

### H2O2 DECONTAMINATION CHAMBERS



### E-BEAM TUNNEL



### GASTIGHT DOORS

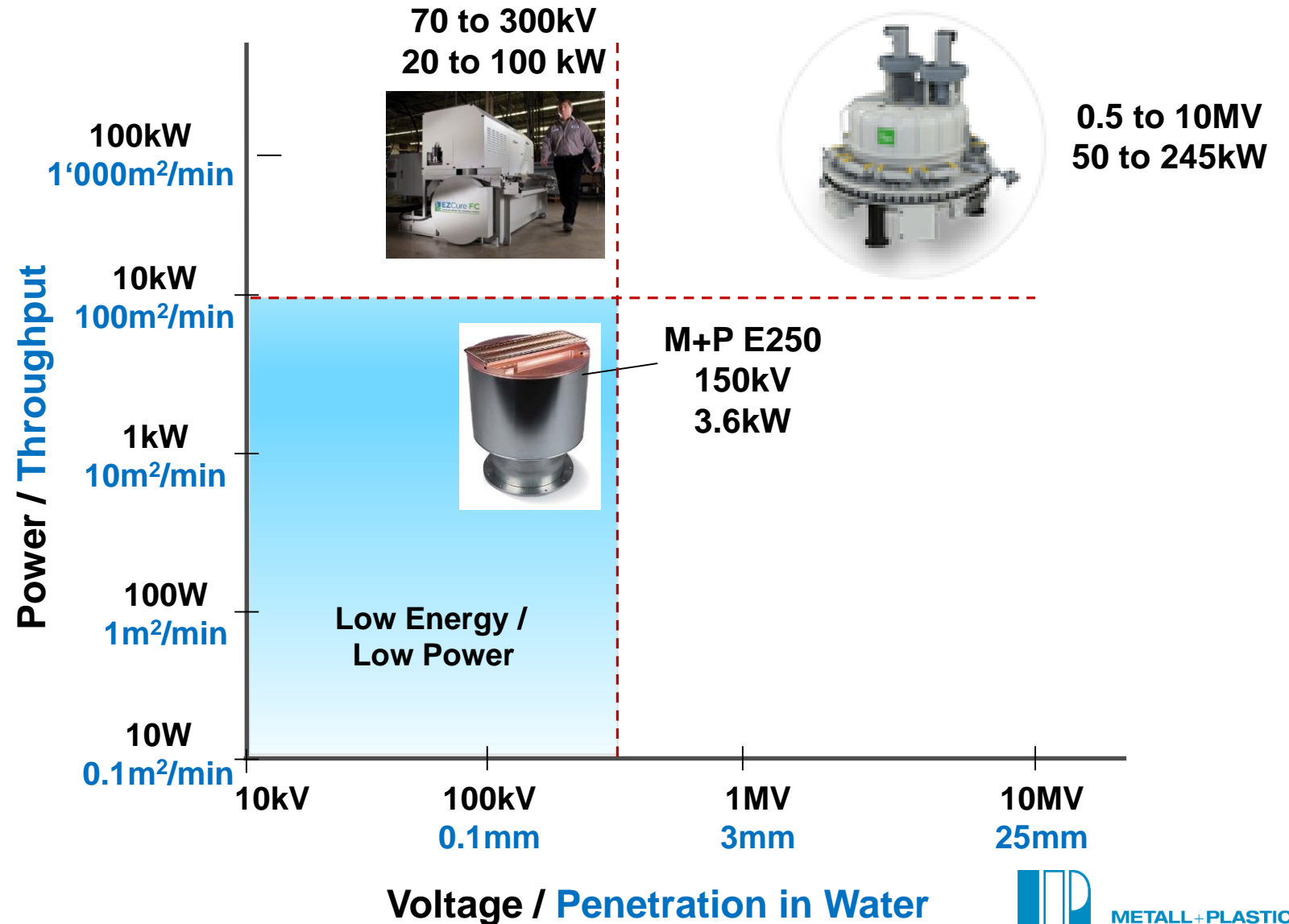


### H2O2 DECONTAMINATION SYSTEM



- 20 years ago the available **E-Beam systems** fell into the top two quadrants
- **Compact E-Beam systems** have since emerged. They allow new applications, especially in the field of sterilization

Sources pictures:  
 top left: Energy Sciences Inc., USA  
 ESI EZ Cure FC  
<http://www.ebeam.com/>  
 top right: iba, Belgium  
 Rhodatron TT300  
<http://www.iba-industrial.com/>



## Characteristics

- **Energy:** 60 to 300 keV (most common 70 to 200 keV)
- **Power:** up to 10 kW – most common up to 5 kW
- **Beam shape:** rectangular 200 mm to 500 mm or  
circular with diameter 10 mm to 100 mm

## Capabilities

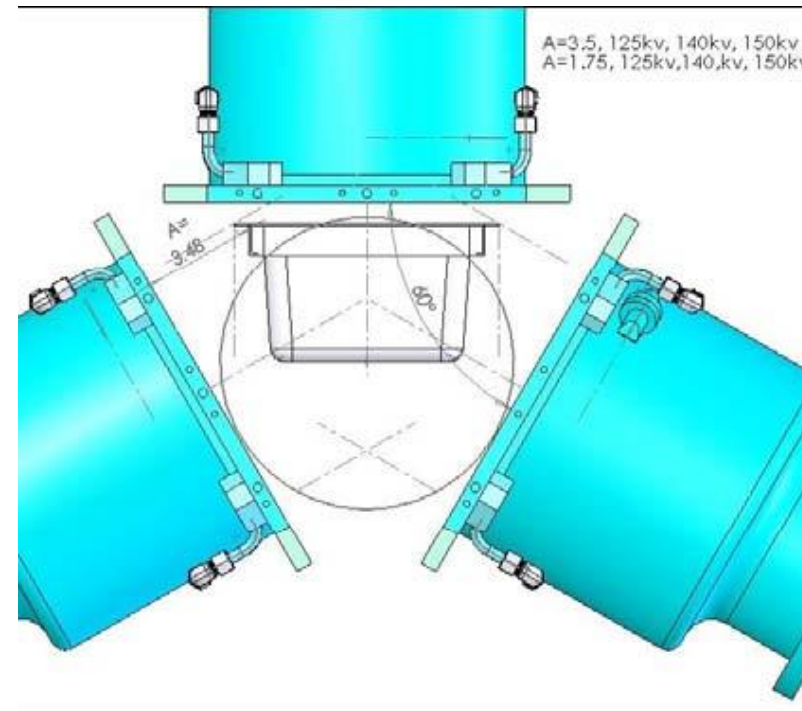
- **Penetration in matter:** a few  $\mu\text{m}$  to 0.5 mm (most common up to 0.25 mm)
- **Throughput:** 1  $\text{m}^2/\text{min}$  to 100  $\text{m}^2/\text{min}$

The **first application compact E-Beam** has made possible: **Surface decontamination of pre-sterilized Tubs** with nested syringes

The Tubs are pre-sterilized and wrapped in a bag. During unpackaging the surfaces may get contaminated – consequently all **surfaces** need to be irradiated with a minimum dose of 25 kGy.



Tub

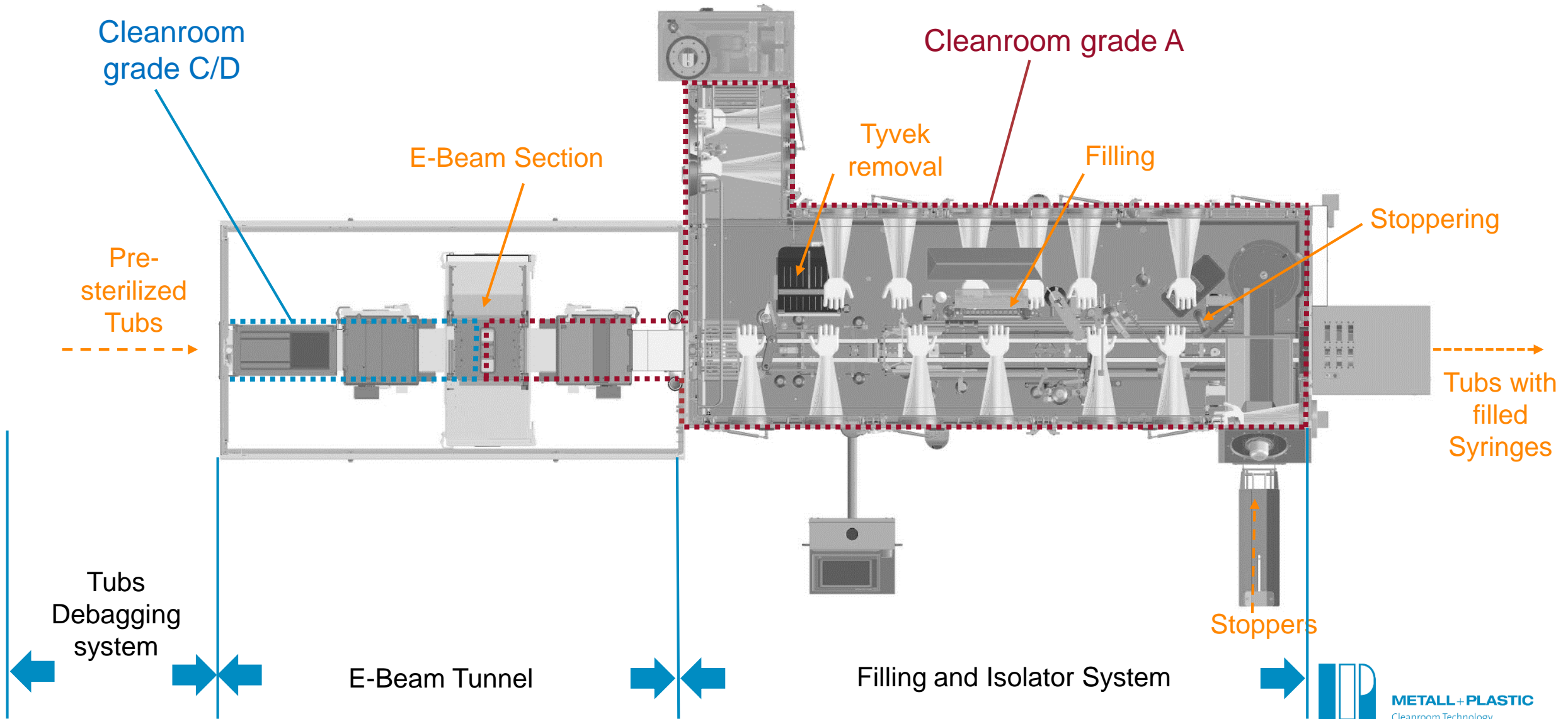


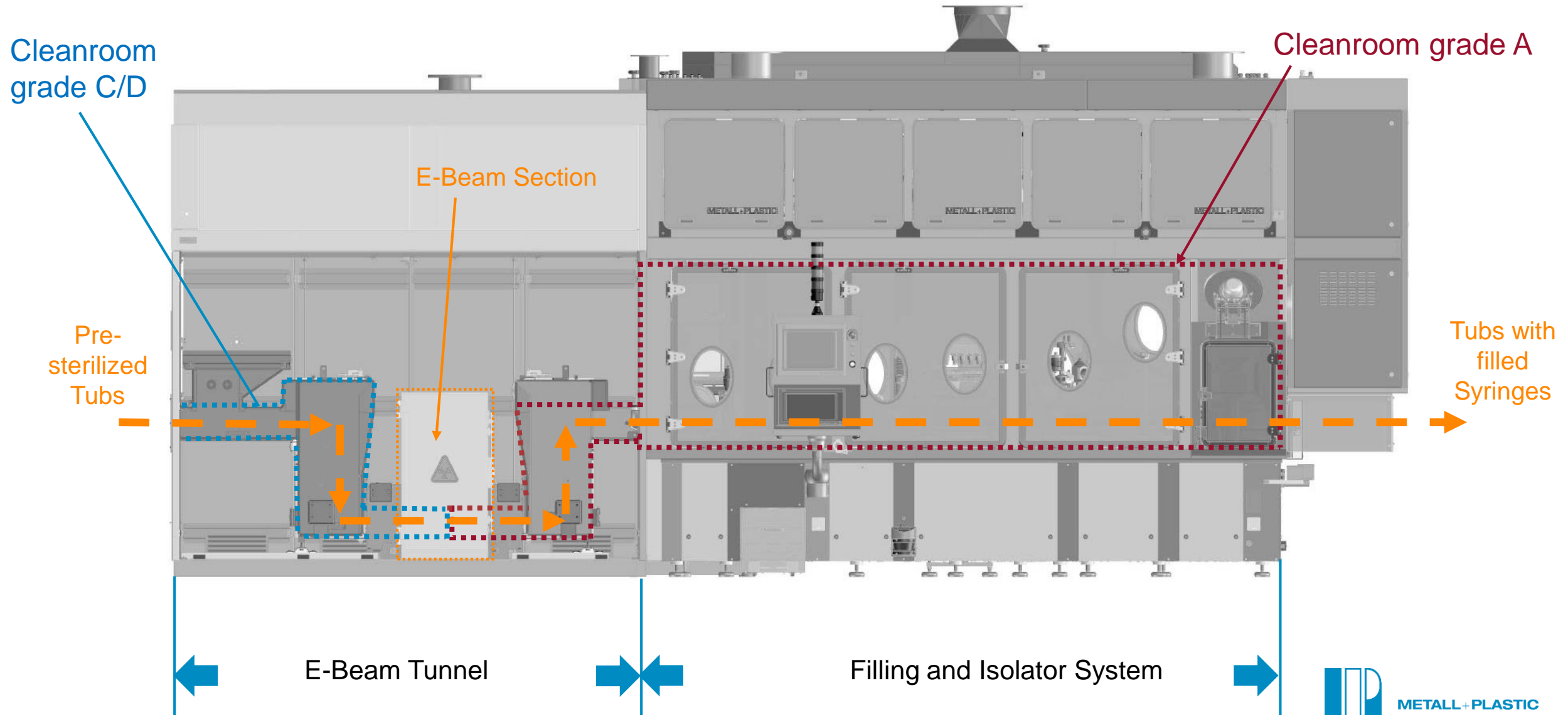
Triangular Emitter arrangement

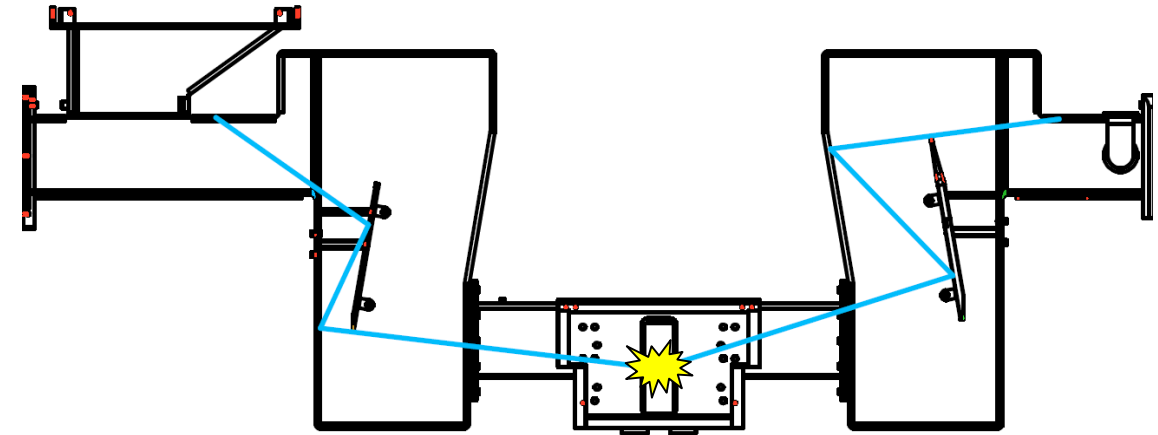
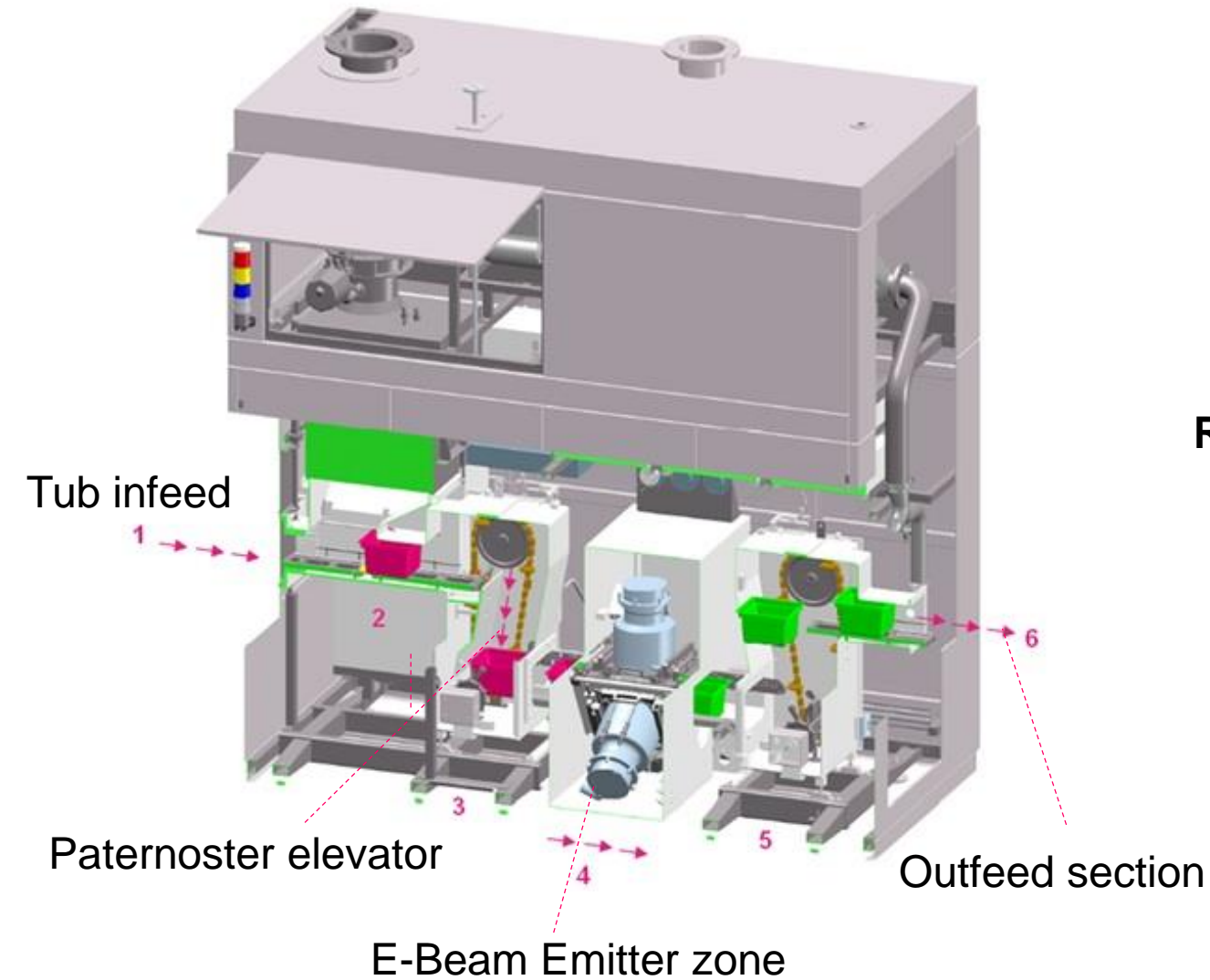
The current **installed base** of all manufacturers: approx. 30 units

The first installation took place in early 2000

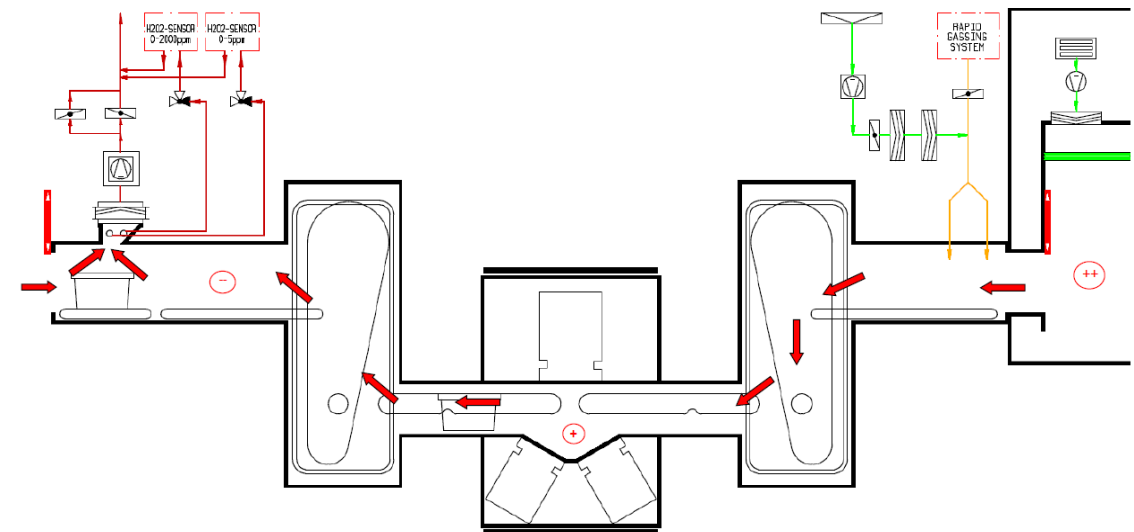








**Radiation shielding:** Depiction of minimum of 3 bounces before radiation leaves shielding



**Controlled airflow** caused by pressure cascade

## Pros and cons **as seen by the user**

Source: Case study: Utilizing Electron Beam Surface Decontamination to Transfer Sterile Syringe Barrels into an Isolated Aseptic Syringe Filling Line, Oliver Vogt, PHARMACEUTICAL ENGINEERING, January/February 2010

### Pros

- Highest **microbial kill power** due to matter penetration
- Power controlled through **beam control parameters**
- Continuous **high speed** process (up to 6 tubs per minute)
- Validation and dose requirements well defined (ISO 11137)
- **Commercially available** technology
- No consumables

### Cons

- **High capital cost**
- **Complex technology**
- Ozone produced

# Alternative to E-Beam Tunnel: Vapor hydrogen peroxide (VHP) surface decontamination

OPTIMA

A batch of Tubs are exposed to a VHP decontamination cycle with the outer bag still in place. Then the whole batch can be moved into the filler and the outer bag needs to be removed inside the filler.

## Pros

- Proven **effectiveness of the VHP cycle**
- Critical areas of the equipment protected

## Cons

- **Limited** maximum filling **speed** due to time consuming VHP cycle
- **Capital cost** of chamber for VHP cycle
- **Manual operation** of loading of chamber
- Not an off-the-shelf solution

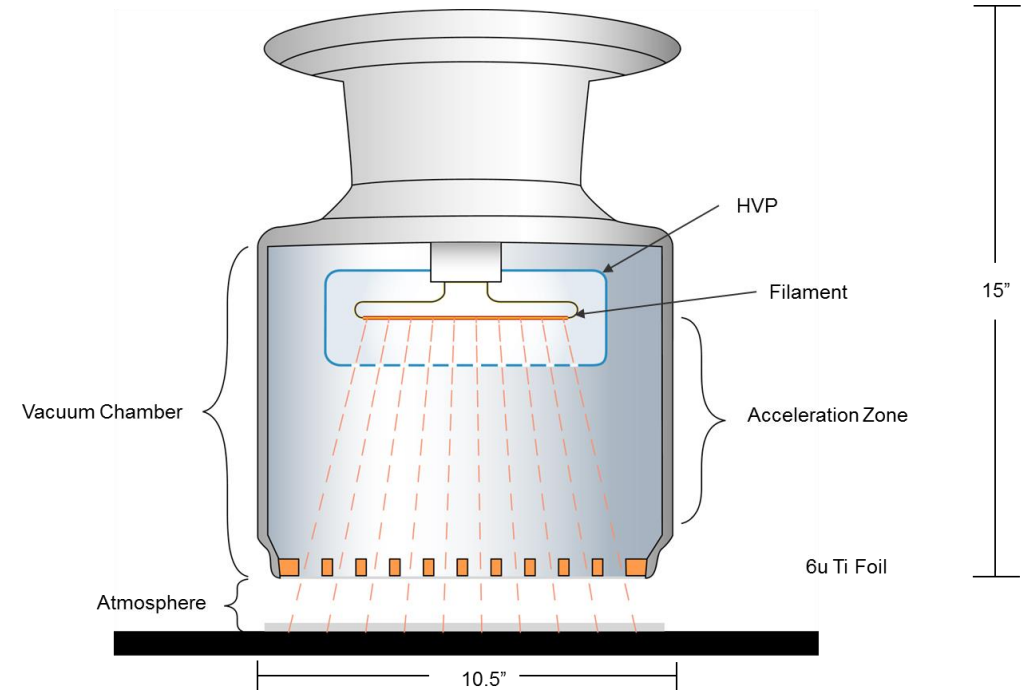
→ Conclusion: all in all **not an attractive alternative**



From the application of the decontamination of pre-sterilized Tubs we can deduce some **key success factors** of applications using **compact E-Beam systems**:

1. E-Beam must have a **unique advantage** over other technologies
2. **Throughput** of objects to be treated must be high – given the high capital cost
3. Treatment of **surfaces** or **thin webs**

- Originally developed by AEB in the United States
- **Features**
  - Hermetically sealed - no external vacuum pump needed, simple replacement in the field
  - Compact dimensions allow easy integration into some machinery
- **Technical Specification**
  - Maximum voltage 150 kV
  - Maximum power: 3.6 kW
  - Beam width 22.1 cm
  - Specifically designed to be easily refurbished



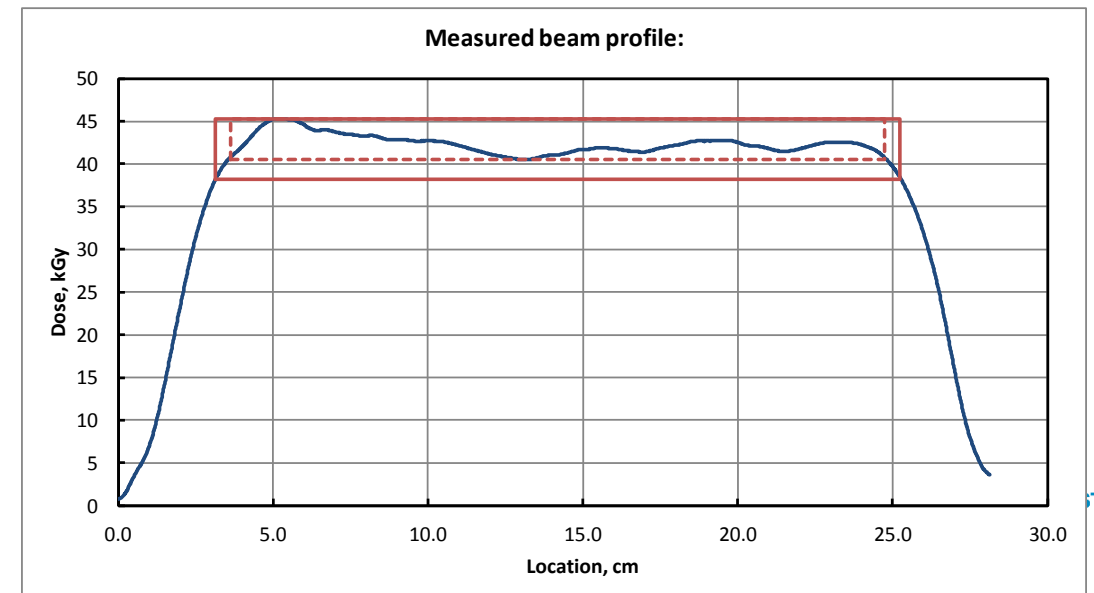
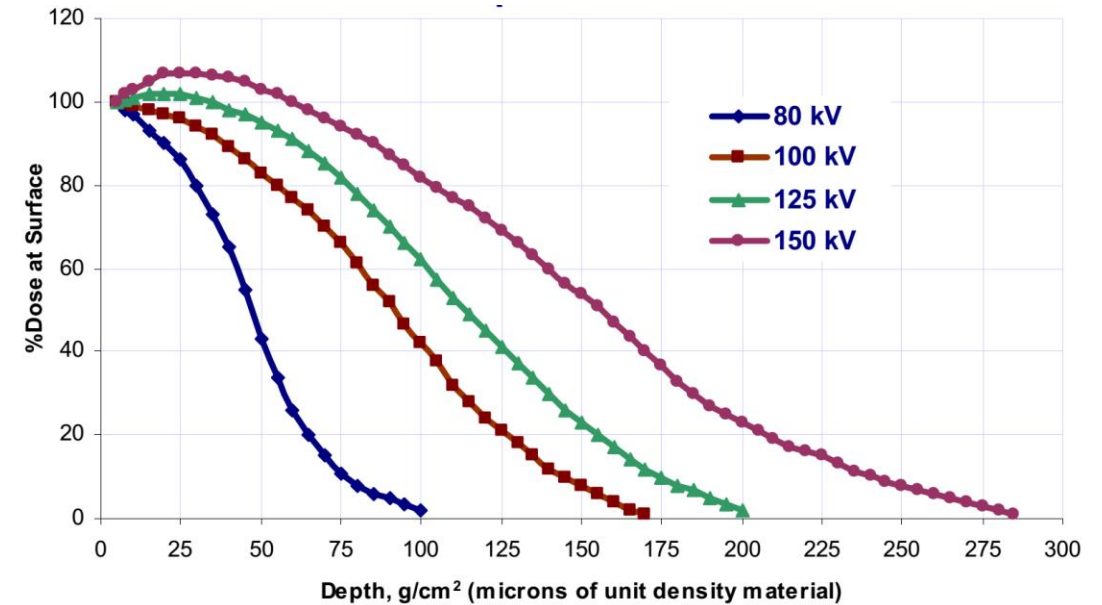
## 1. Penetration

Graph showing depth dose in water. The depth dose allows to determine the voltage, which is necessary to overcome a given air gap or to penetrate the outer Tyvec foil but not the inner one

## 2. Width of the electron beam

Given the triangular E-Beam arrangement, in order to decontaminate homogeneously the full width of the Tub, the width of the electron beam needs to be about the same size

## 3. K value, is a constant that allows to calculate the surface dose as a function of the current (mA) and the transport speed of the Tubs (m/min)



The compact E-Beam application **Surface decontamination of pre-sterilized Tubs** meets the **key success criteria**

1. **Unique advantage** Highest microbial kill power
2. **High Speed**
3. Decontaminates the **surfaces** of the Tub

This **justifies** the relatively **high capital cost** and the **complexity** of the equipment

## Challenges for Metall + Plastic

- Personalized medicine: smaller batch sizes, higher flexibility e.g. large range of Tub sizes and shapes
- New version under development that takes account of these requirements

