

NEW APPLICATIONS FOR ACCELERATORS IN PHARMACEUTICAL PROCESSES

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Applications and Utilization of Accelerators

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GETINGE LINAC TECHNOLOGIES – ORSAY, FRANCE

www.linactechnologies.com

SUMMARY

- **GETINGE LINAC TECHNOLOGIES SAS**
- **SterStar™ LOW ENERGY SYSTEM**
- **SterBox™ MEDIUM ENERGY SYSTEM**
- **BENEFITS FOR THE END-USER**
- **PRACTICAL ASPECTS OF INTEGRATION IN THE PHARMACEUTICAL PROCESS**



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GETINGE LINAC TECHNOLOGIES SAS

- GETINGE LINAC is situated in Orsay, 20 km south of PARIS, FRANCE:
 - Surface area : 1 150 m²
 - 27 employees
 - Sales (2008): 8 500 K€
- Member of the GETINGE group
 - 12000 employees worldwide
 - Sales (2008) : 1852 M€



GETINGE LINAC

GETINGE LINAC

MeVAC

KeVAC

LINAX

CIRCE



GETINGE LINAC

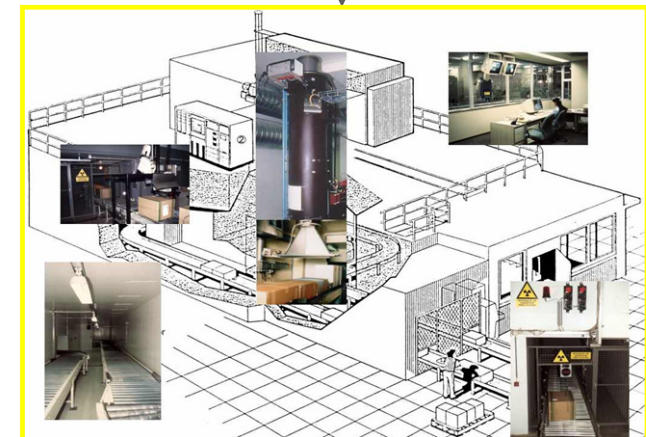
GETINGE LINAC

SterBox

SterStar

LINAX

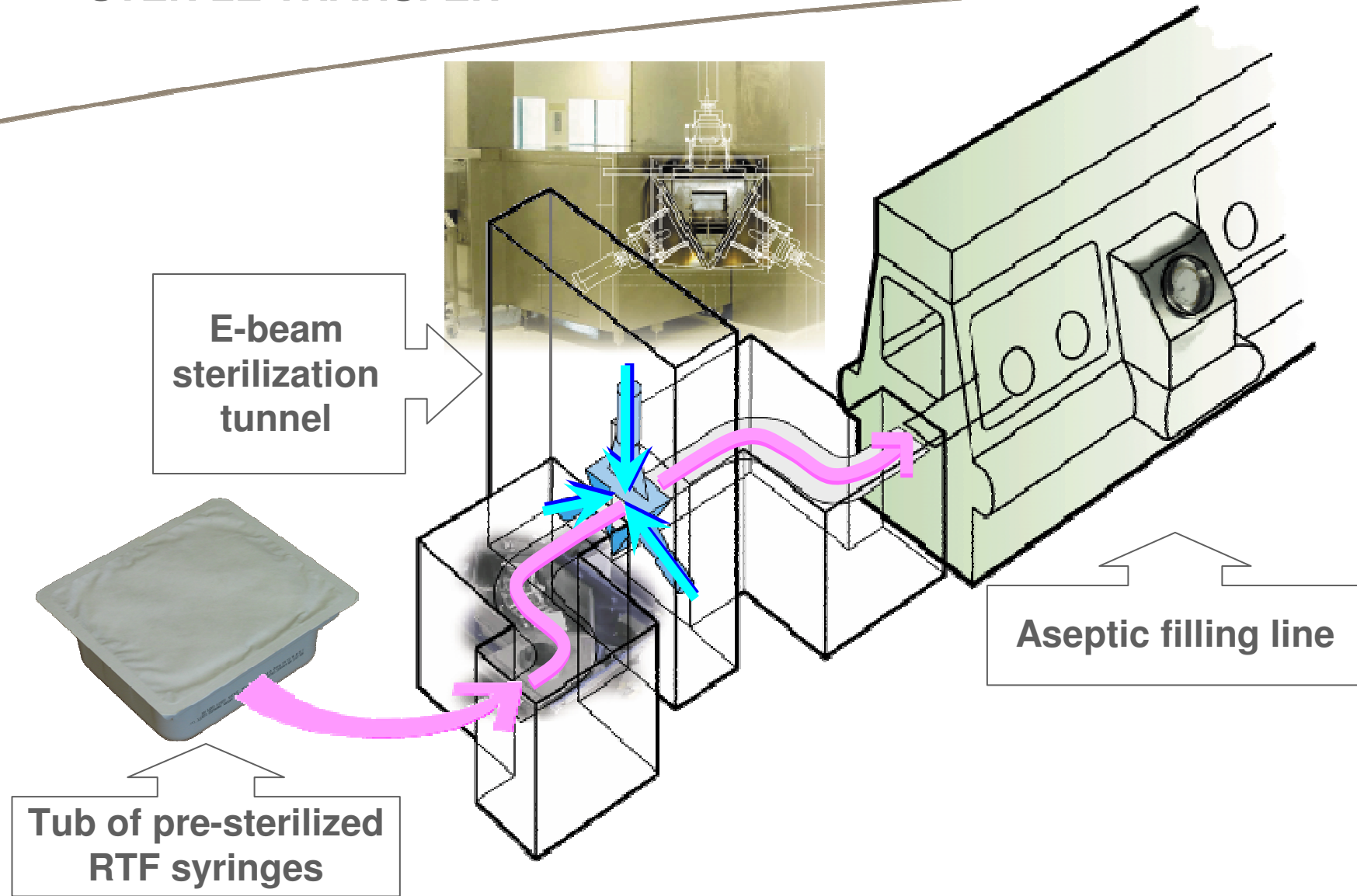
SterRoom



SterStar™ low energy system
STANDALONE IN-LINE
SURFACE STERILIZATION TUNNEL

SterStar™ E-BEAM TUNNEL STERILE TRANSFER

GETINGE
LINAC

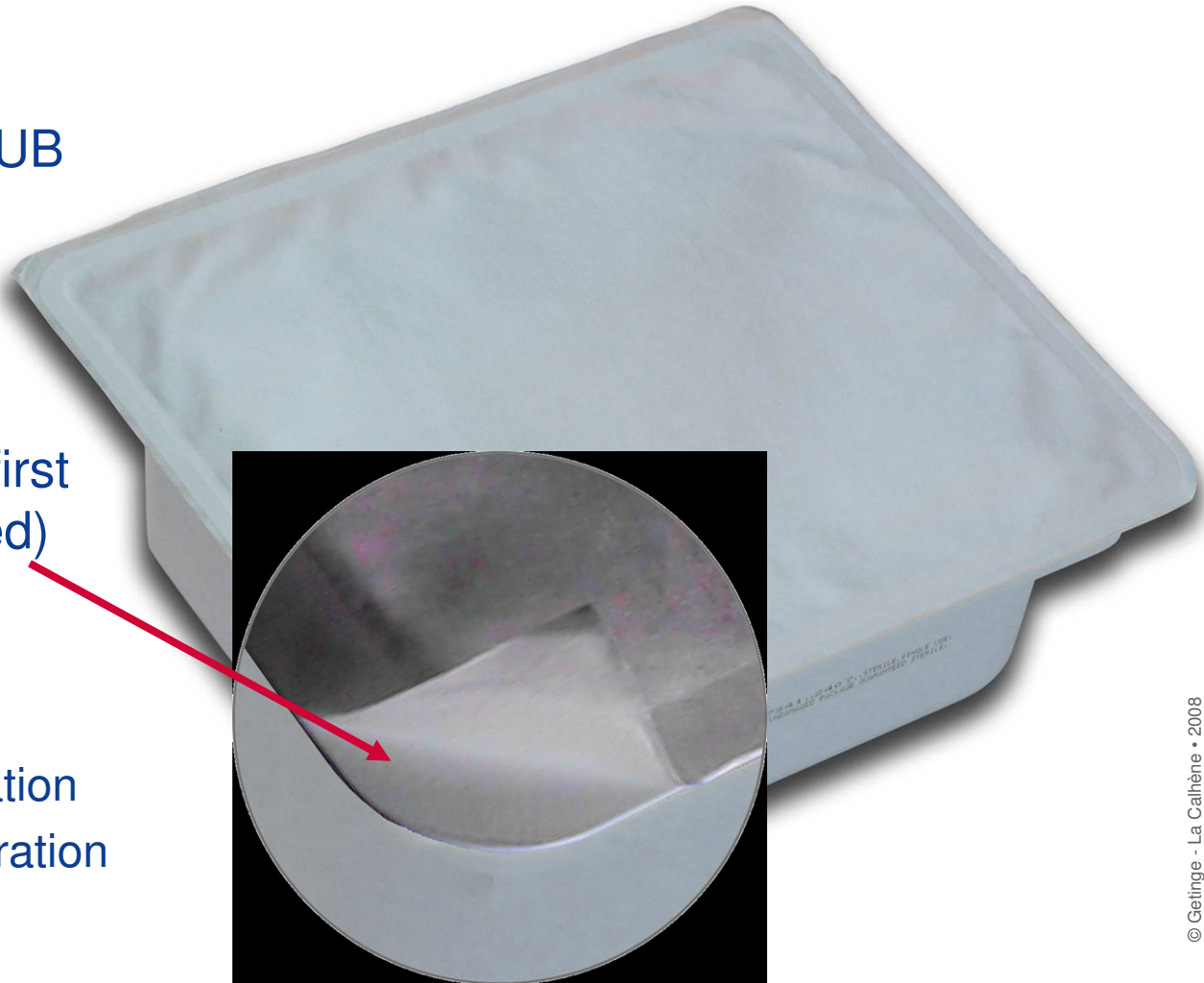


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SterStar™ E-BEAM TUNNEL FOR SURFACE DECONTAMINATION

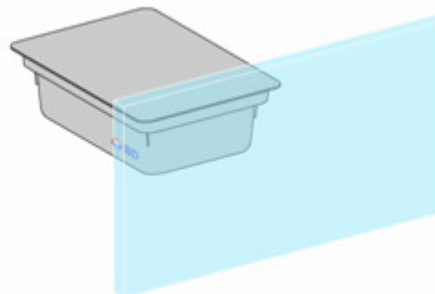
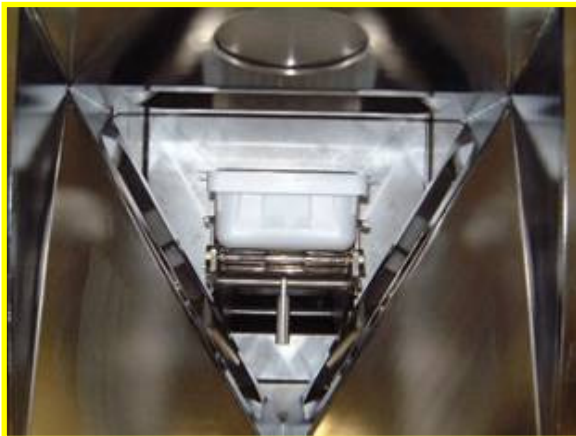
GETINGE
LINAC

- TO STERILIZE TUB SURFACE
- INCLUDING HIDDEN AREAS
(25 kGy under the first Tyvek® guaranteed)
- WITHOUT
 - Glass coloration
 - Ozone accumulation
 - Tub (ink) deterioration



CONFIGURATION

3 low energy e-beam accelerators are installed at 120° to sterilize the entire surface of the TUB.

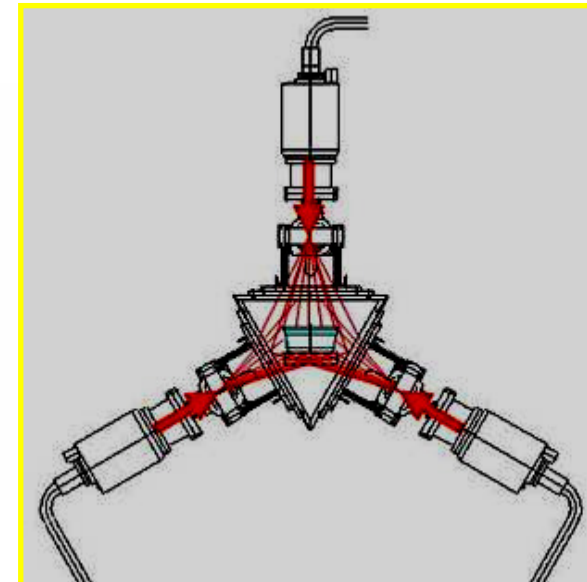


Continuous throughput :

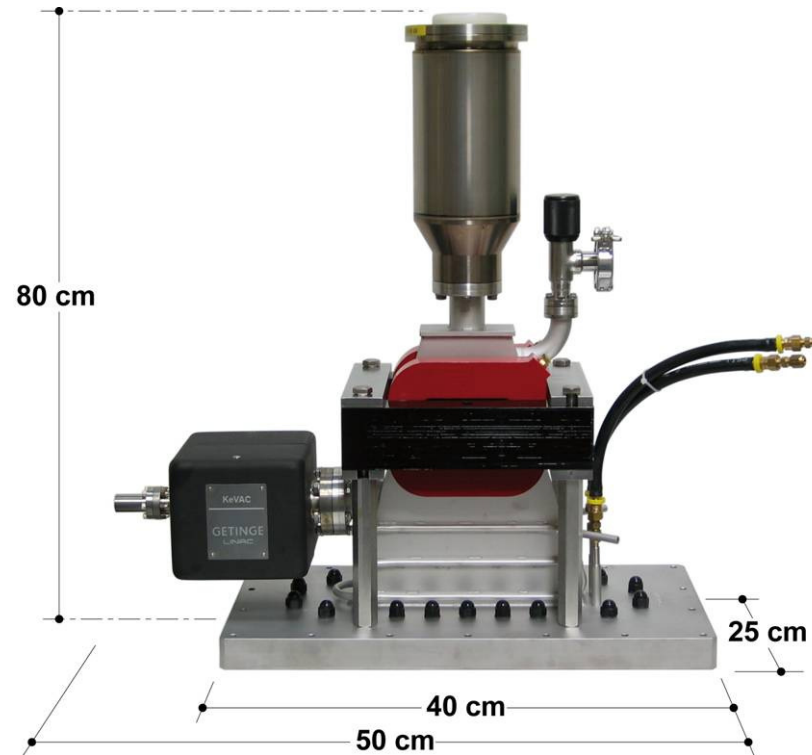
6 tubs per minute,

i.e. 36,000 syringes per hour (100 syr. tubs)

57,600 syringes per hour (160 syr. Tubs)



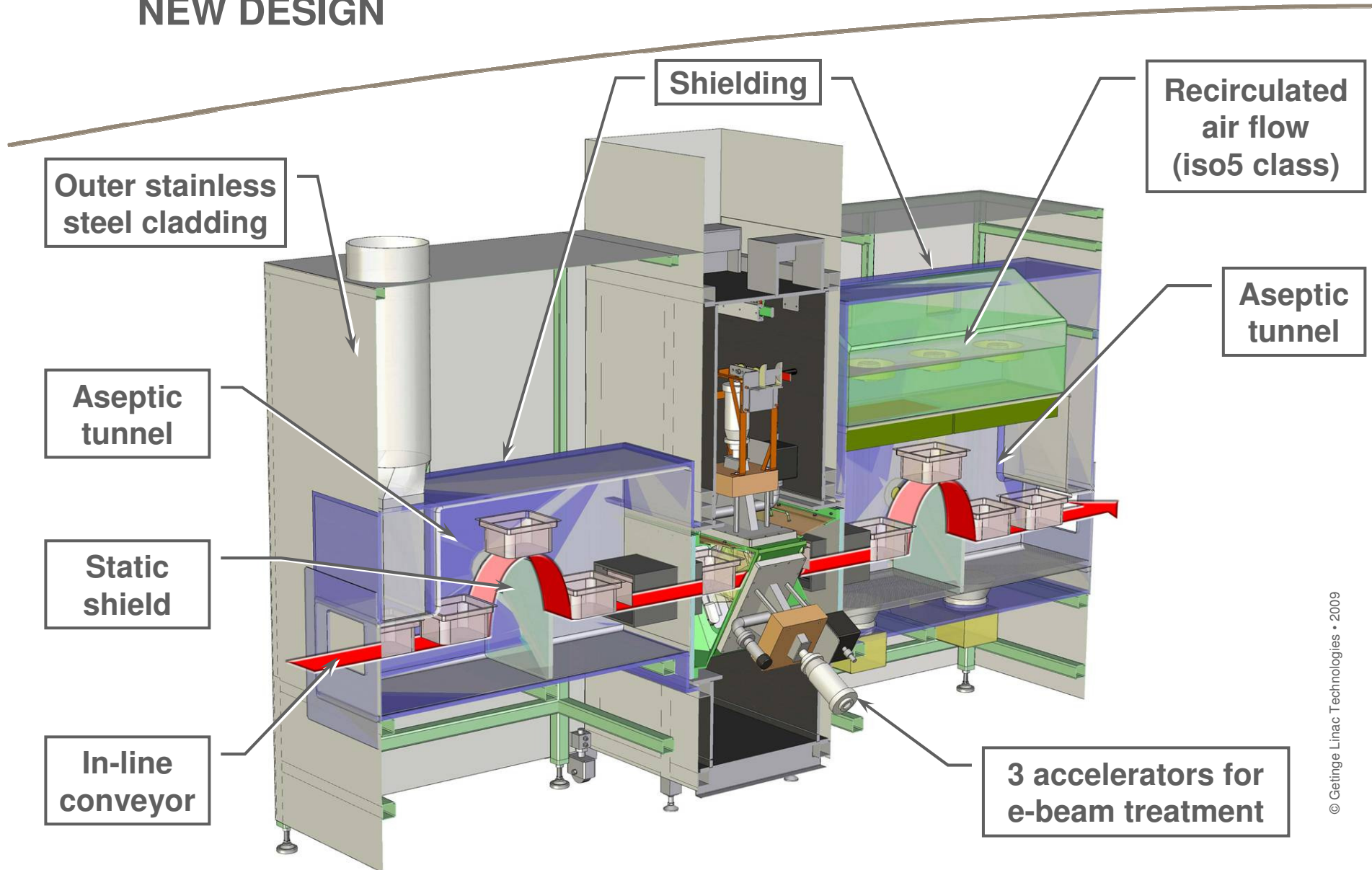
KEVAC LOW ENERGY ACCELERATOR



Energy :	variable between 10 and 200 KV
Power :	800 W
Average beam current :	from 0 to 5 mA
Scanning width :	from 7 cm to 20 cm (according to tub size)
Conveyor speed :	according to the throughput
HV generator :	continuous voltage

SterStar™ E-BEAM TUNNEL NEW DESIGN

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SterStar™ IN PRODUCTION SUITE

Stainless Steel Outer Cladding



Filling Line

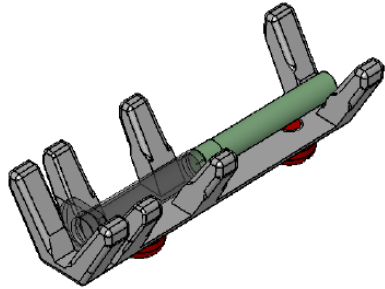
Tub Input

27 e-beam units of this type are installed or under construction throughout the world. 19 of these have been supplied by Getinge Linac.

SterBox™
medium energy system
STANDALONE IN-LINE
TERMINAL STERILIZATION TUNNEL

STERBOX TERMINAL STERILIZATION

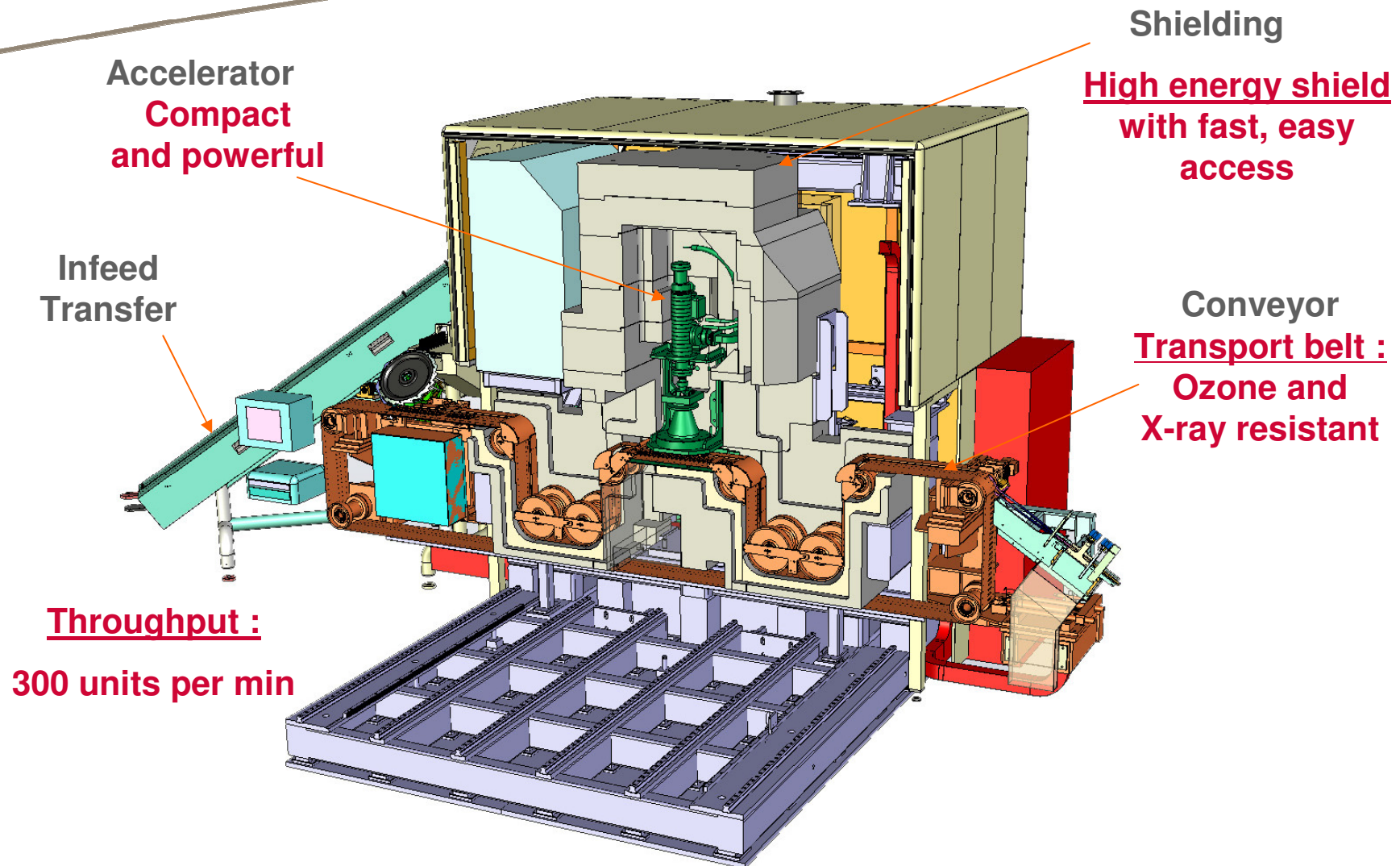
Terminal sterilization of filled or empty syringes and vials, inline with high speed filling machine.



Terminal sterilization of
medical devices



STERBOX Design Scope



MEVAC accelerator inside shield

- Energy :** 5 MeV
- Power :** 5 kW
- Average Beam Current :** 1 mA
- Scanning Width :** Bidirectional scan XY
- Scanning Area :** Up to 10 cm x 10 cm
- Conveyor Speed :** Up to 10 m / min
- HV Generator :** Solid State Modulator



STERBOX in the workshop

SterBox Video



STERBOX REFERENCES

2 Units are installed for a US customer



BENEFITS OF E-BEAM FOR THE PHARMACEUTICAL MANUFACTURER

- In-line in-house machines for surface or core sterilization:
 - **Logistics & Capital Assets Economy**
- Continuous treatment with recording of the GMP parameters:
 - **Quality & Safety**
- Flexibility of tuning for better dose distribution:
 - **Quality & Economy**
- Reliability and easy maintenance on site:
 - **Quality & Economy**
- Stand alone equipment: easy to install - can be moved.
 - **Economy**
- Low operating costs.
 - **Economy**
- Packaging sterilization just prior to filling:
 - **Quality & Economy**

■ VALIDATION

- ✓ System is completely validated
 - ✓ Simple to validate
 - ✓ Traceable
 - ✓ Recordable
 - ✓ Meets standards

■ DOSIMETRY / STERILIZATION

- ✓ Complete sterilization : 7 log decrease
- ✓ Regular dosimetry checks

■ THROUGHPUT AND ROBUSTNESS

- ✓ Fast continuous sterilization

■ ENVIRONMENTAL IMPACT

- ✓ « Green » technology
- ✓ No chemicals used
- ✓ Minimal exhaust products
- ✓ Comparatively low energy consumption

■ INTERFACING WITH PROCESSES

- ✓ Fully integrated in the production process both upstream and downstream

■ PHARMA GMP DOCUMENTATION

- ✓ FS / SDS / HDS / IQ / OQ / PQ... electronic signatures and printed paper files

***We make life
safer for you***

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