



Tofflon



Design Considerations for Aseptic Fill-finish Isolation System

By Asher Zeng

Tofflon Senior Solutions Manager



Tofflon Group Senior Solution Manager

- 5+ years of experience in project management, quality management of the pharmaceutical equipment (filling machine, freeze-dryer, L&U, isolator, VHP sterilizer, capping machine).
- 4+ years of facility validation experience (Such as HVAC, tunnel, filler, freeze-dryer, L&U, isolator, VHP, autoclave, capping, bung processor etc.).
- 4+ years of isolator design experience.
- Deep understanding of GMP regulations of pharmaceutical manufacturing.

Topic

Key Design Considerations for Aseptic Fill-finish Isolation System



MONDAY | 28 APR | 2025



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About the Speaker
Mr. Asher Zeng



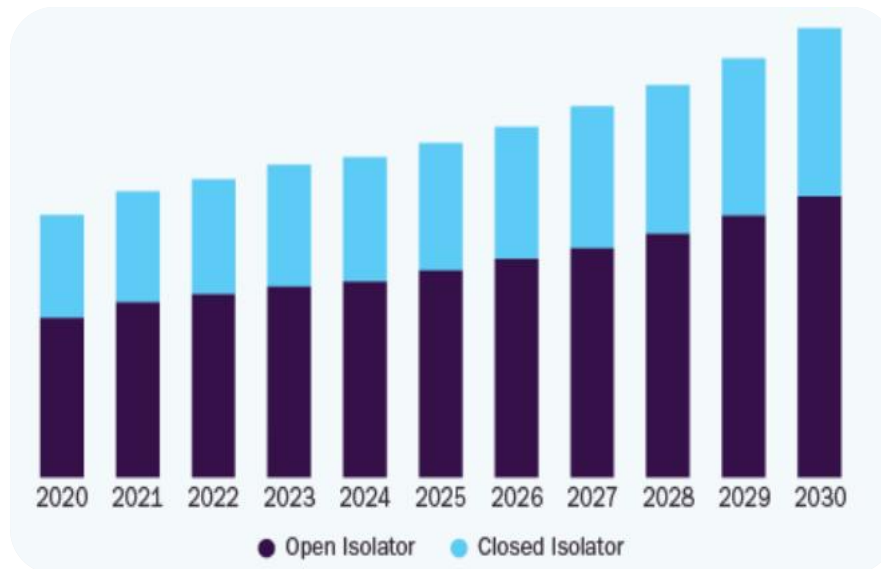
Let's Join

Tofflon AGENDA

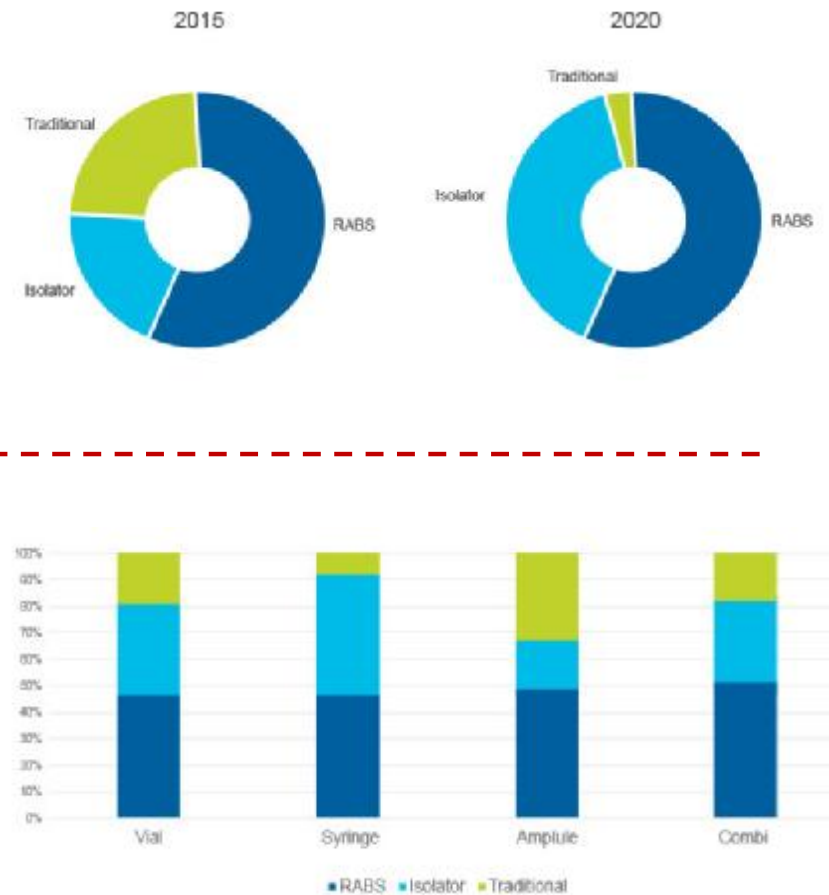
- u Market Requirements & Emerging Challenges**
- u Key Design Considerations for Aseptic Isolation Systems**
- u Case Studies & Lessons Learned**
- u SUMMARY, Q&A**

1 New Requirements & Emerging Challenges

Tofflon Isolator Demands



2020 ISPE Barrier Survey: Although the regulatory bar continues to rise, the hurdles for entering the world of advanced aseptic technology have been lowered.



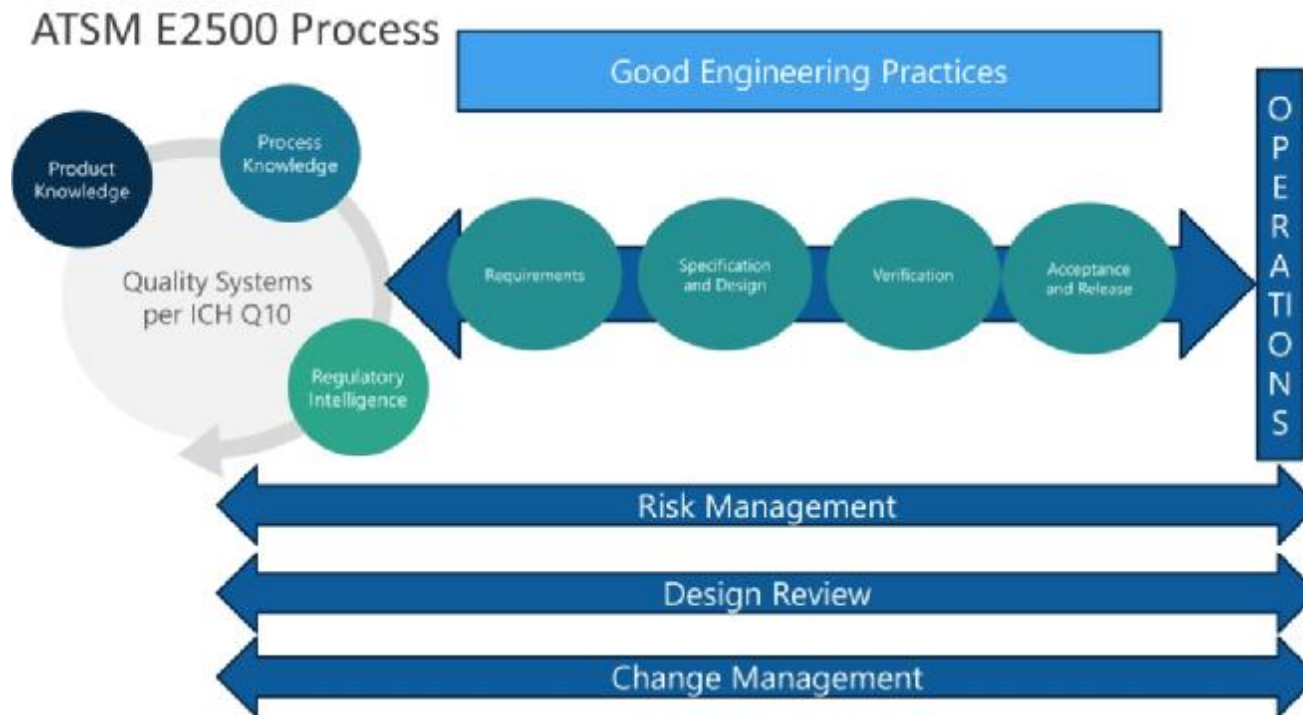
Tofflon Market Challenges

- I **Regulatory Tightening:** EMA, FDA, WHO, PICS, NMPA, other regulators
- I **Future-proof solutions for complex biologics** (e.g., ATMPs, mAb)
- I **Supply chain implications** **(Regional Tariff)**
- I **Agile and flexible demands for small-batch or collinear production**
- I **GMP VS EHS** Etc.,



2 Key Design Considerations for Isolation Systems

Tofflon Requirements Compliance



- I EU GMP Annex 1
- I FDA 21 CFR Part 11
- I P/ICS
- I WHO



Tofflon QRM for Design.....

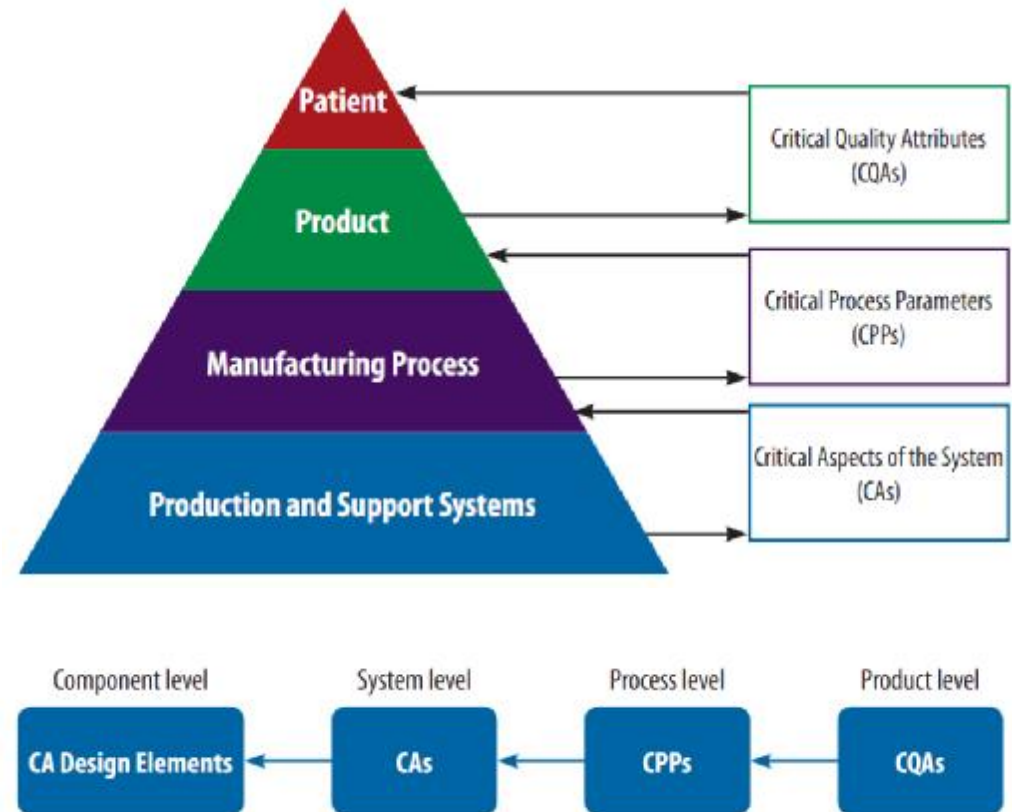
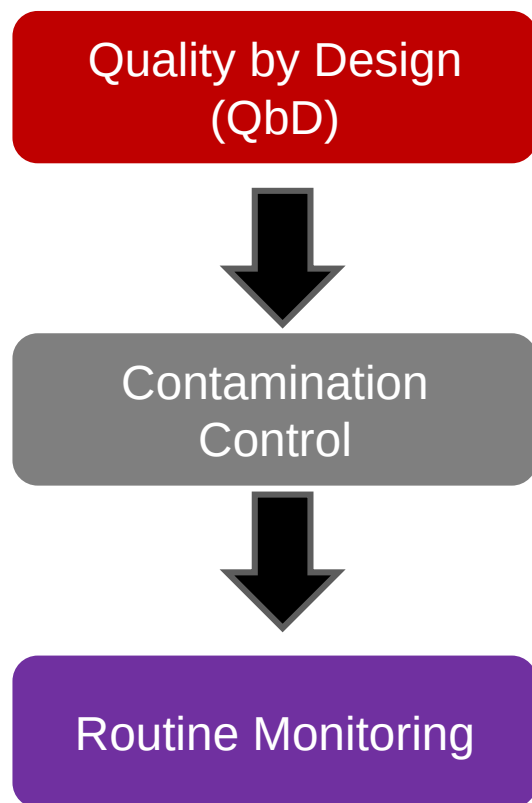


Figure 6.1.1-2 Flowchart of Developmental Process

Tofflon Aseptic Processing Considerations

Physical Environment & EM

I Classification, Background, Velocity, Air visualization.

Material Transfer

I Material transfer pathway, Hold time.

Ergonomics & Interventions

I Glove monitoring, EM, sampling, rejections.

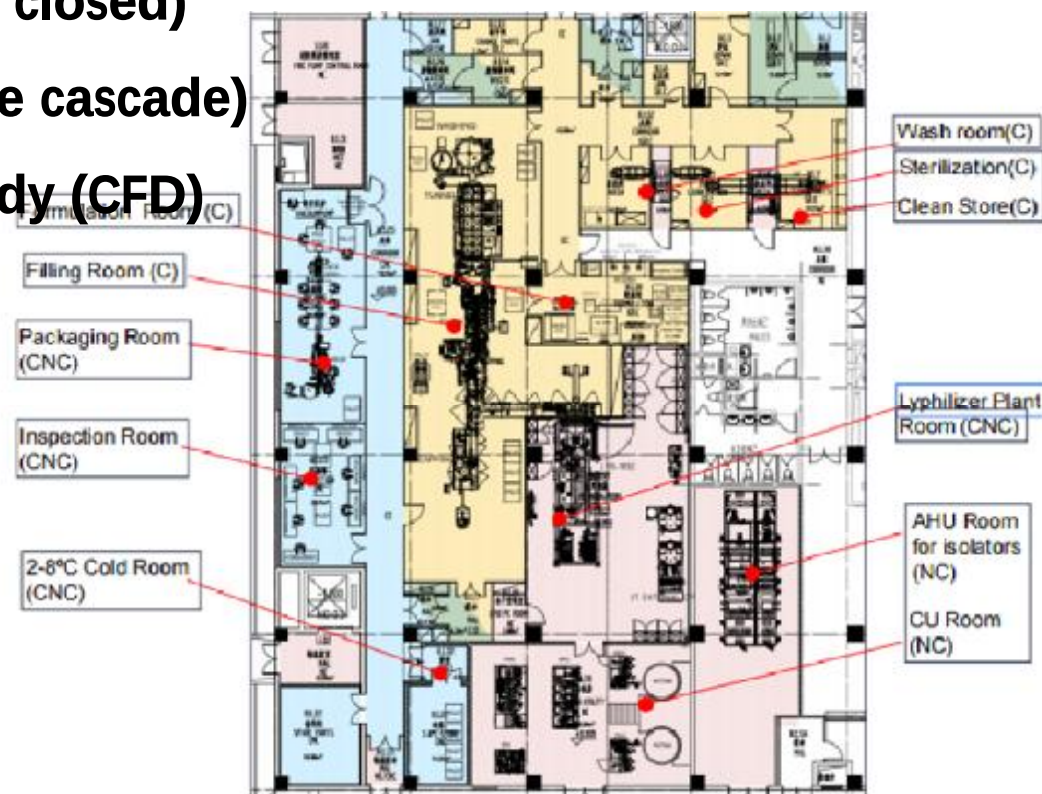
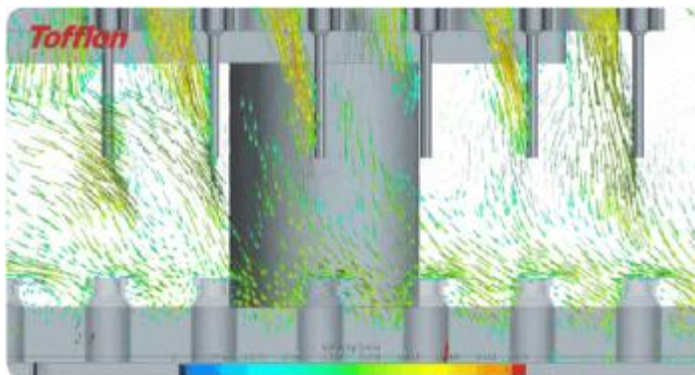
Sterilization & Validation

I Acceptance criteria. Aseptic Process Simulation

Etc.,

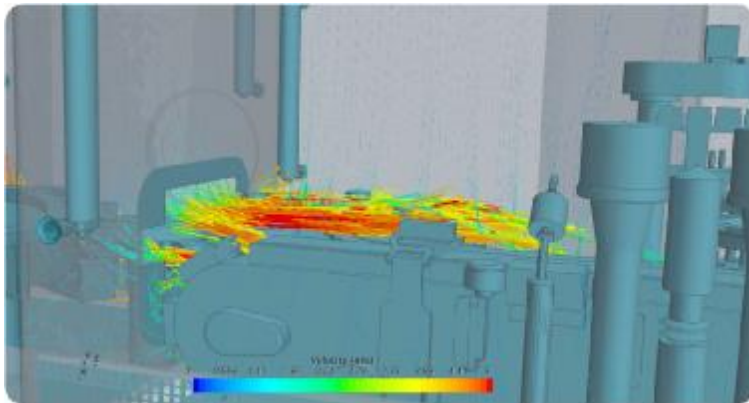
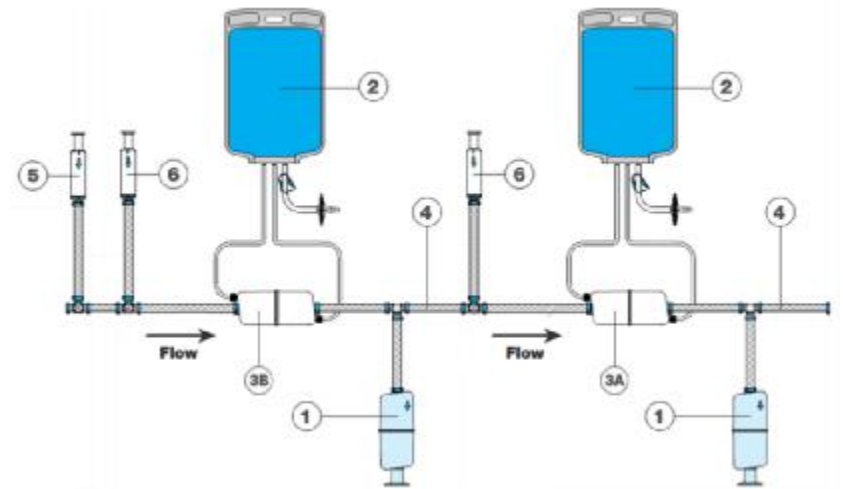
Tofflon Physical Environment & EM

- I ISL (Background) , ISL (Open or closed)
- I Processing Integration (Pressure cascade)
- I First-air principle & Airflow study (CFD)
- I Continuous EM
- I Critical Utilities



Tofflon Material Transfer

- I Sterile boundaries & Systematic integrity (including PUPSIT)
- I Single-use filling set to eliminate the potential cross-contamination
- I Material transfer / NTT



Tofflon Ergonomics & Intervention

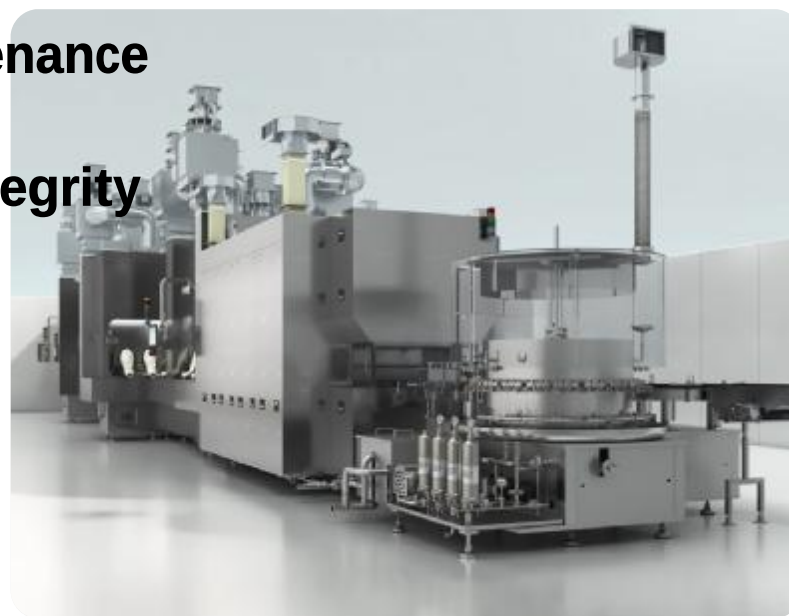
- I Intervention Risks--**Processing matching with full lifecycle consideration (from setup, operation to clear-up)
- I Glove Monitoring**
- I New-techs application--** Automation with Robotics, BFPCs, etc.,



Automation with Robots

Tofflon Other Considerations

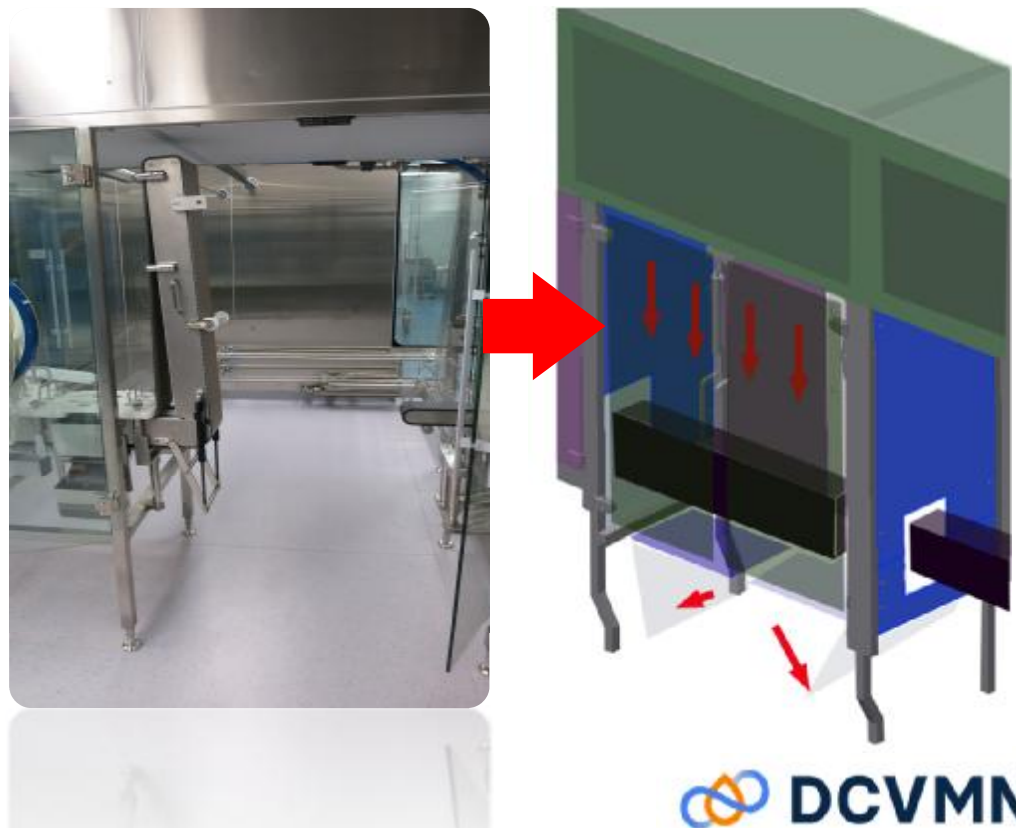
- I Easy for Cleaning & Maintenance**
- I Bio-decontamination, Sterility Maintenance**
- I Key Parameter Monitoring & Data Integrity**
- I Rapid changeover for personalized therapies**
- I Validation required Etc.,**



3 Case Studies & Lessons Learned

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- | **Cross over filling area received FDA 483 for airflow disrupting.**
- | Air turbulent on mouseholes
- | Cross-contamination during stoppers transferring.
- | Others



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- | Others



4 SUMMARY

A close-up photograph of two hands, palms up, holding a small, glowing heart. The hands are positioned in the center of the frame, with the heart resting between the palms. The background is a soft, out-of-focus white.

ALL FOR YOU