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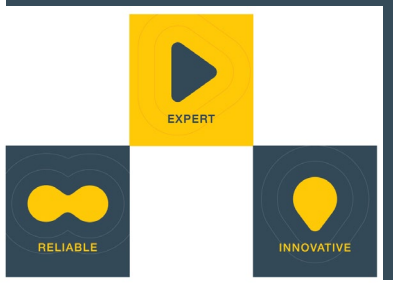
ETHYLENE OXIDE STERILIZATION NEW INDUSTRY DEMANDS



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Mediplast Team

- **Introduction Patrick Lewis,** 30+ years, first 10 years Synergy (Steris). Setup own company
- 20 year working with the US multinationals, including Steris, BSC, Medtronic, Sterigenics,
- Currently, working with Stryker, and most of my time with Mediplast.
- **Management & QA groups**

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Mediplast Sterilization Options

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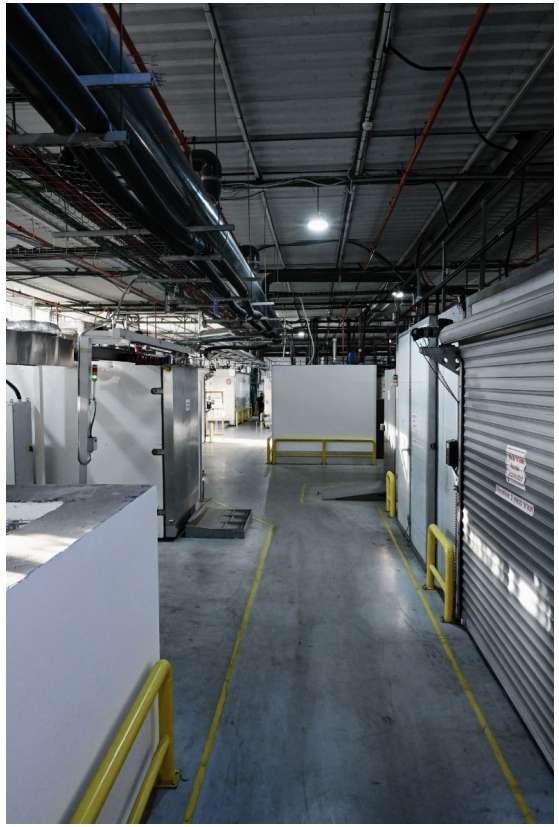
RELIABLE
INNOVATIVE



Before we get into the main presentation.

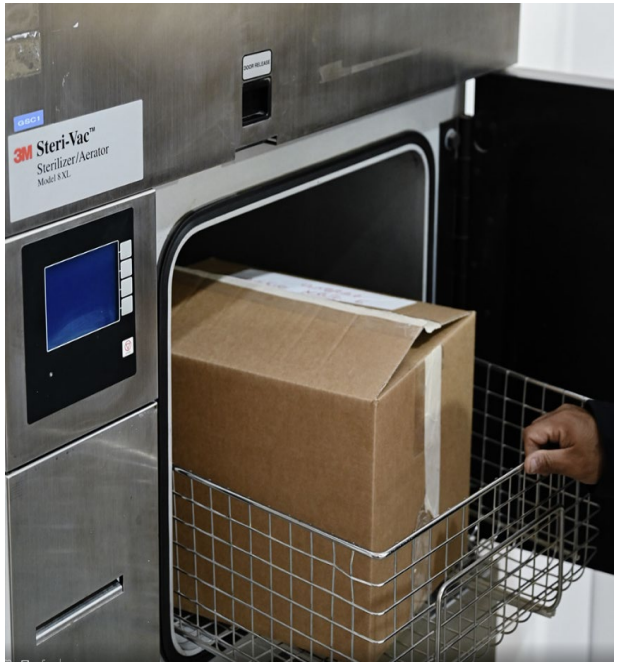
In consultation with the demands from our startup customers

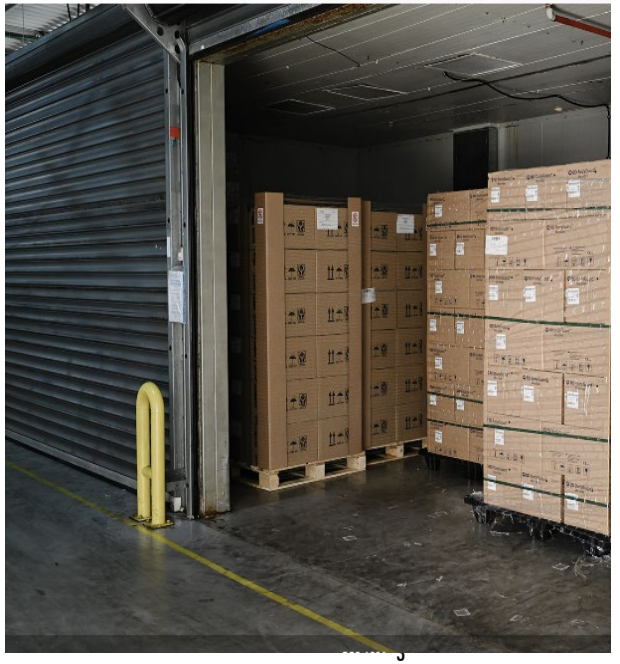
We have recently added 2 small 3M sterilizers 220L

New 4 & 7 pallet lines, added to existing 3, 4, 7, 8, 10, & 15 pallet lines

Additional Aeration rooms, new offices meeting rooms.

In the process of adding a new sterilization technology to the site





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Market Overview

- **Here to talk about EO and the new industry demands**
- Even with current pressures, **EO still growing**
- The more we move to custom kits, with hundreds of components, only need one component cannot be irradiated
- **No choice full kit has to be EO sterilized.**
- **Radiation effects polymers,**

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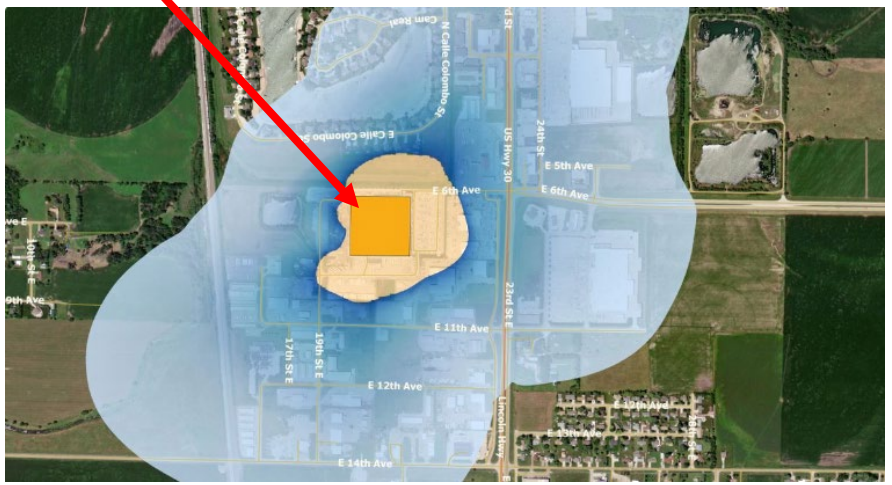
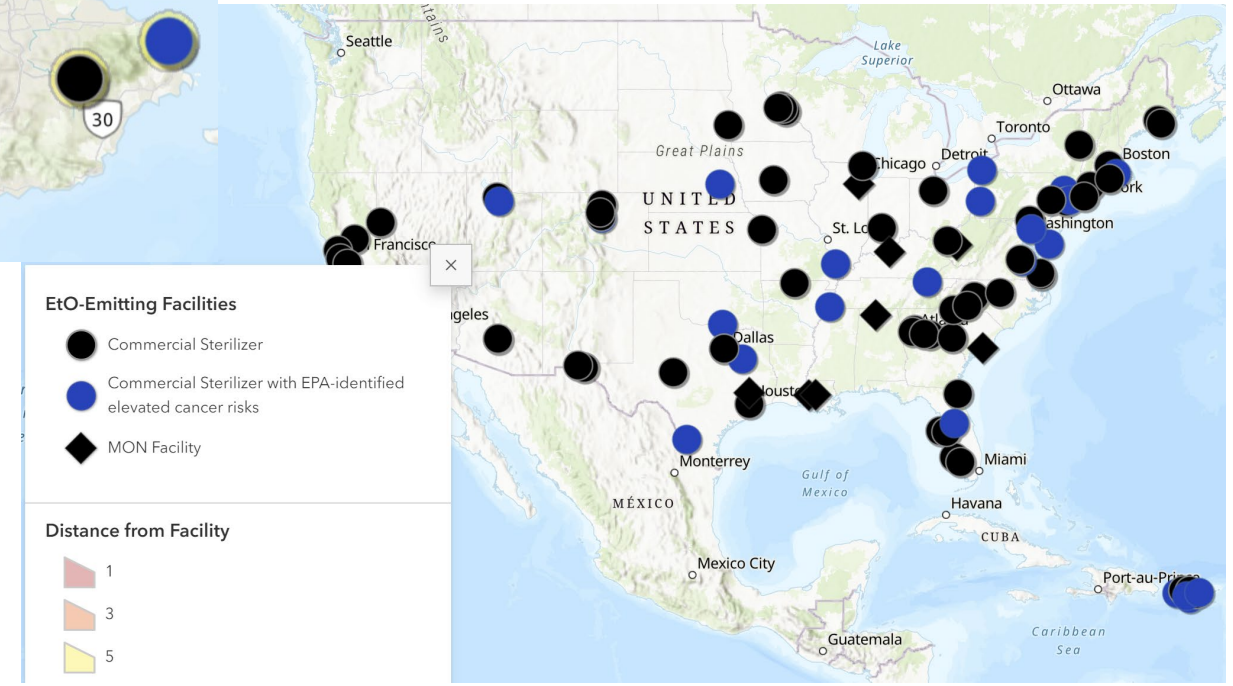
New US industry demands for EO Sterilization

- **Two major industry changes,**
- **First changes** **New US legislation for EO sterilization, (Released last week,)**
  - Ongoing battle for the past 6 years: US EPA & US Public with Medical Device Sterilization Industry
  - Started with Sterigenics Willowbrook site forced closure in 2019.

- **US EPA** (Environmental Protection Agency)
- Names Multinational Companies / Locations etc:





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New US legislation March 2024

- **SUMMARY OF KEY CHANGES**
- EO Sterilization cycle gas concentration, **reduced from today's level >600mg/l**. Target use reduction 25 - 50%
- Reduction in EO exposure limits for people. Decrease from 1 Part per million PPM (to proposed 10 **PPB**illion.)
- Better Facility Design. Improved EO Treatment systems.
- Continuous monitoring of EO Levels.
- **NOTE:** Proposed 10PPB US EO limit, impact every person in contact with the supply chain of the product

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EO Product Residuals

Second major change.

- **EO Residuals**: STD Amendme1 of the standard establishes new allowable limits for EO and ECH n Medical Devices. Effective from December 2019.
- **Differentiates between allowable limits for Adults and Infants according to body mass**.
- Previously – limits were defined based on an Adult body mass of 70 kg (almost everything 4mg of EO / Device
- Now – Device Manufacturers need to specific the population group as the basis for defining those limits.
- **Adult. --average body mass of 70 kg**
- **Child. --average body mass of 10 kg**
- **Neonate Baby. --average body mass of 3.5 kg**
- EO and ECH tolerable exposure limits. For limited exposure products – up to 24 hours exposure

Adults 70kg current limit	**Neonate baby 3.5kg new limit**
4 mg EO / day	**0.2 mg EO / day**
9 mg ECH / day	**0.4 mg EO / day**

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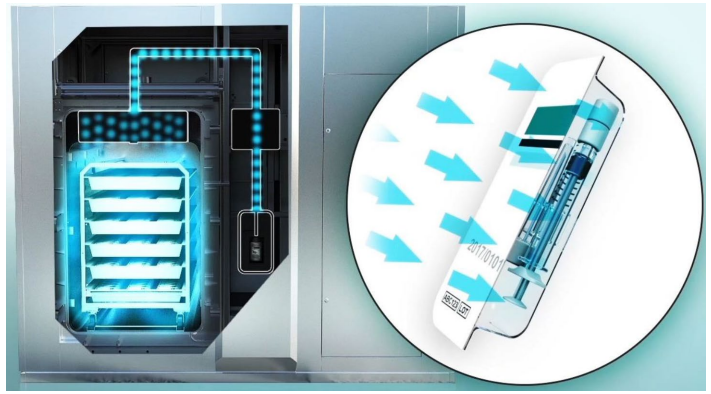
VHP (Vaporized Hydrogen Peroxide)

- **Another change:** (not major like the others but still of interest)
- **HYDROGEN PEROXIDE GAS PROCESS** (Very Similar to EO, Equipment Validation etc.)

  - **January 2024 FDA** changed VHP to an Established Category A. For sterilization of single use devices.
  - Recognized ISO 22441 as the validation Standard.

  - Today only 1 or 2 companies in the world supplying this technology.



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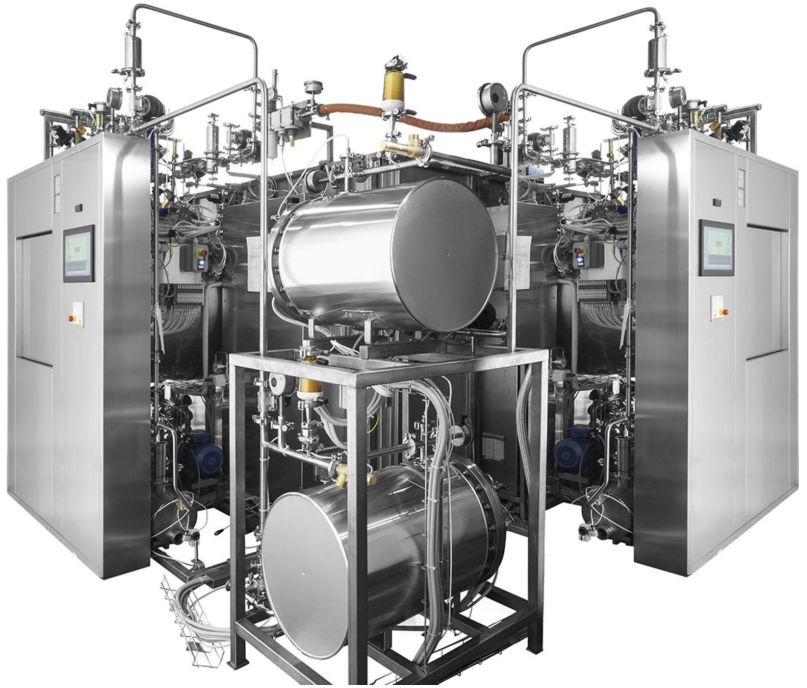

- **Key Considerations**
- High capital equipment cost
- **Cannot sterilize in cardboard no boxes**.
- Sterilize in primary packaging (Pouch-blister)
- **Not really designed for large volume processing yet based on cost**.
- **Mediplast** are currently partnering to offer this technology as an option
- **Mediplast** will offer this soon as real option for our Israeli customers

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- **Obviously not here just to show the problem**
- **We have a plan forward**

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Mediplast Technology upgrade based on US EPA

- EO Treatment Systems. Old technology - Chemical Scrubbers - Replaced with Catalytic Abator:
- Additional Aeration rooms high and low temperature
- Improved site layout to protect people & capture all airstreams from facility.
- Pleased to say Mediplast are now in compliance with the changing legislation for an EO sterilization facility.

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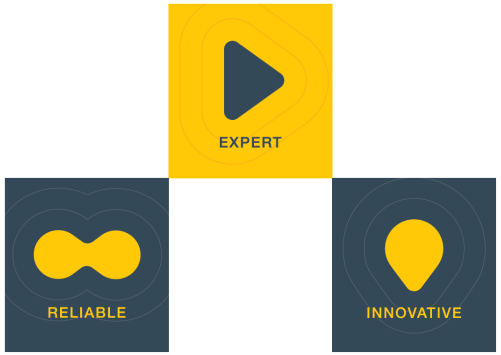
Mediplast Case Study



- **Second Major Change. EO reduction & Product residuals**
- **Case Study 1**
- **Last year we carried out a major cycle development** exercise local manufacturer, there US Multinational partner.
- **This was a health and safety**
- They have global requirement of <0.2ppm of EO in their facility, after sterilization and transportation of the product to their overseas site
- After conventional sterilization cycle, Product tested in their facility had levels >0.2ppm of EO

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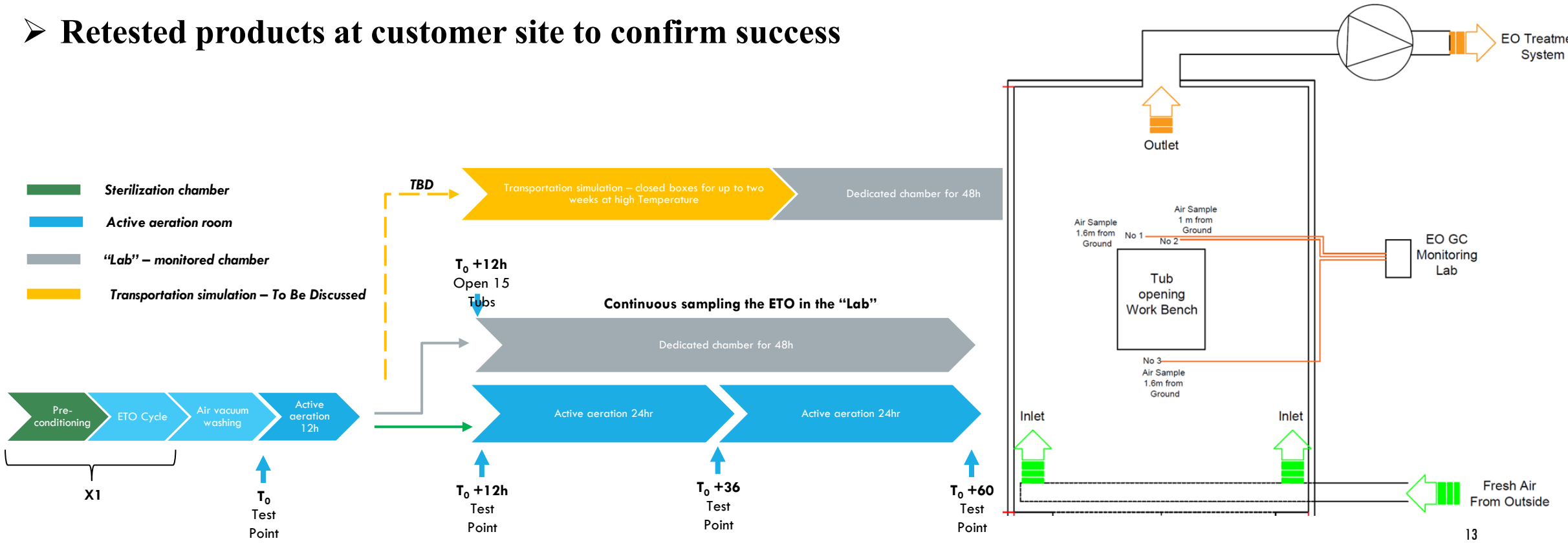
Mediplast Case Study 1

- **Agreed full Study Plan with customer**
- Built test lab to simulate their overseas work environment
- Designed and validated a new innovative EO sterilization cycle
- Simulated Transportation to facility, Measured EO levels after new sterilization cycle, found EO levels well below 0.2ppm
- **Retested products at customer site to confirm success**



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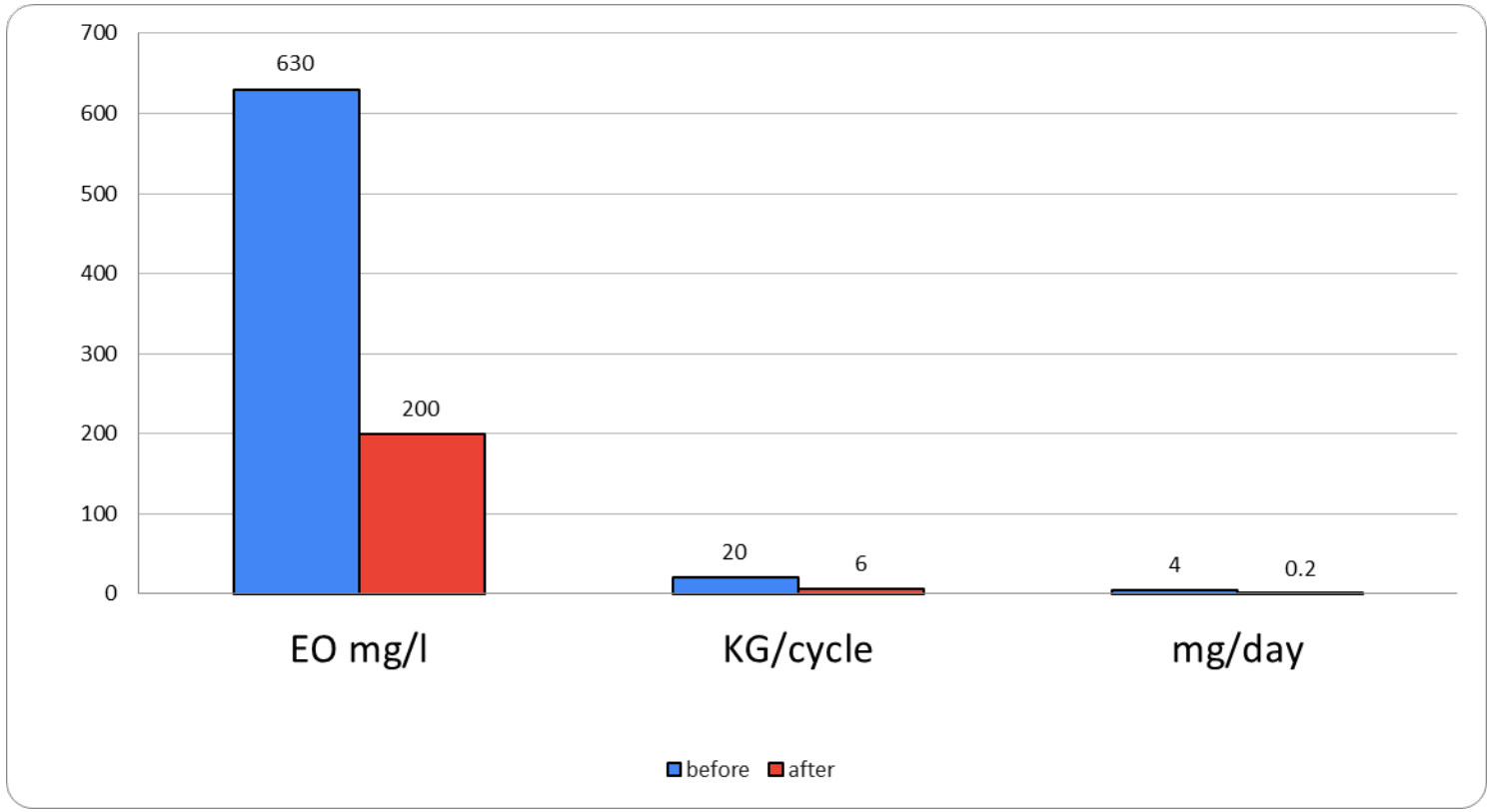
Mediplast Case Study 2

- **Working with an Israeli company**, adoption of the new residual standard for Neonates.
- Large custom packs, lots of tubing various polymers, silicones etc.
- Traditional cycle EO concentration 635mg/l. 10 pallet load, 20kgs EO/cycle. 2kgs EO/pallet processed
- New Innovative cycle designed & tested. validation ongoing, Reduce EO concentration to 0.6 kgs/ pallet



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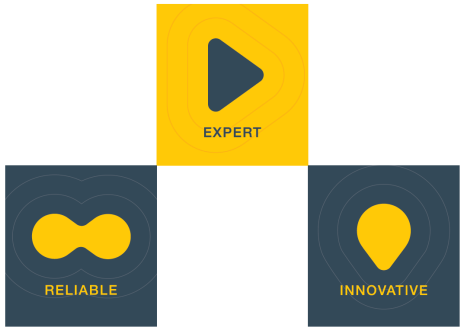
Innovative Cycle already complete



- **Sterile product for cell growth** (EO had effect on growth)
- Completed a low concentration sterilization cycle <150mg/l
- Product already in trials over the world

- **Huge amount of work with combination products**, (drug delivery devices) low concentration cycles,
- Low temperature cycles 30 degC. Already validated and in the market
- This area is growing rapidly,

- **Body absorbable products**
- Today we have a number of customers with temperature / RH sensitive products.
- Designed absorbable into the body, cannot get close to 37DegC (we sterilize are 30-32 degC)
- Already validated and in the market

- These project above all get the additional benefit of compliance with the new EO Sterilization Industry demands

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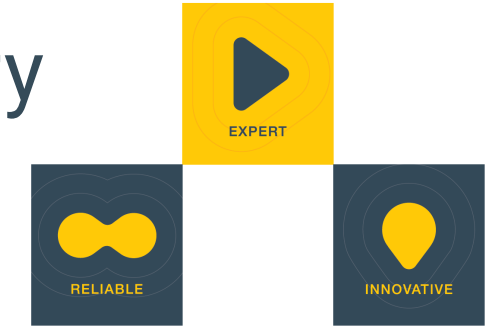
Mediplast, & Israel's Device industry



- **Going Forward as Partners.**
- We have already invested to upgrade our site in line with the industry demands
- We have available sterilization capacity on all size chambers, adding more and VHP
- **We strongly recommend our customers to target EO reduction programs and align new US and EO residuals requirements**
- We are here and ready to help

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Mediplast Going Forward

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RELIABLE
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- THANK YOU
- Please join us on linked in
- **Come visit us in booth number 43 outside**