



# Investor presentation Plan for North America

---

June 2023

Paul Swinney – CEO Tristel plc

Liz Dixon – CFO Tristel plc

Julija Shabanova – CEO Tristel Inc

Heidi Allard – Group FC Tristel plc

# Tristel ULT – approved for sale

---

Notification received 3 June 2023 from FDA:

De Novo request for classification of Tristel ULT has been approved as a class II foam/gel chemical sterilant/high level disinfectant for the reprocessing of transvaginal and transrectal ultrasound probes and skin surface transducers that may contact non-intact skin during use.



As a result of this order, we may immediately market our device.

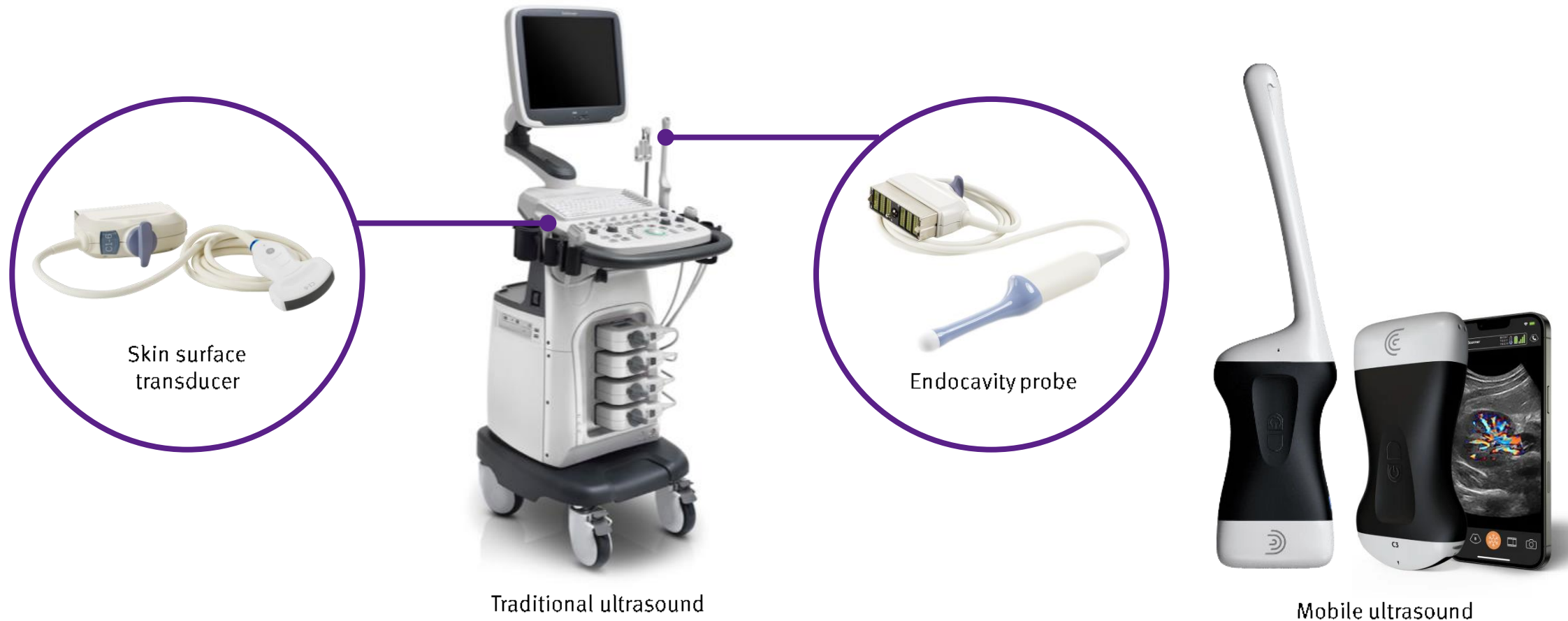
# FDA, EPA, Health Canada: Foundation stones laid

---

- 1) EPA and FDA, Washington
- 2) Parker Laboratories Inc., New Jersey
- 3) Health Canada, Ottawa & Innova Medical Ophthalmics, Toronto
- 4) Tristel Inc., Massachusetts



# Ultrasound technology



# Segmenting the ultrasound market

## The Spaulding Classification



### SEMI-CRITICAL

#### Endocavity ultrasound probes

Contact with mucous membrane or non-intact skin.

High-Level Disinfection (HLD)

### NON-CRITICAL

#### Skin surface ultrasound transducers

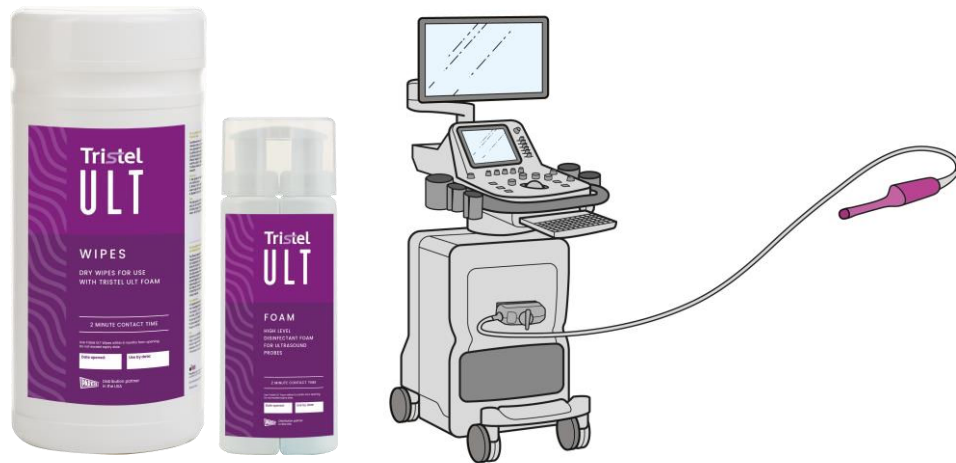
Contact with intact skin.

Intermediate or Low-Level Disinfection (ILD/LLD)

# The regulatory agencies

## Shaping our marketing and brand strategy

### USA - FDA



#### HIGH LEVEL DISINFECTION

Endocavity probes, and skin surface transducers  
that may contact non-intact skin during use

FDA APPROVAL

### USA - EPA



#### INTERMEDIATE LEVEL DISINFECTION

Skin surface transducers  
and ultrasound console

EPA APPROVAL

# Our manufacturing partner for the Americas + distribution partner for ultrasound

## Parker Laboratories Inc.

- Founded in the 1950's
- Family owned
- World leader in the manufacture and marketing of accessories and supplies for the ultrasound and electromedical markets
- Aquasonic 100, leading global brand of ultrasound transmission gel
- US nationwide distribution network
- FDA approved manufacturer
- Revenue est US\$60M



Aquasonic 100



Parker Laboratories Inc. Headquarters, Fairfield, New Jersey

# A strong partnership

Combining our products: used in every ultrasound procedure

## Tristel

High Level and Intermediate  
Level Disinfection



- 1) 215,000,000 ultrasound scans in US (Company estimate)
- 2) 271,000 traditional ultrasound consoles in US (Competitor data)



Traditional console and mobile ultrasound (1,2)

## Parker

Ultrasound Gel and  
Probe Covers





# Tristel and Parker business model

## Tristel HLD Global Brands:



- ULT - Ultrasound probes & transducers  
Parker distributes in North America
- OPH - Tonometers, pachymeters and lenses  
used in ophthalmology  
Tristel free to select route to market
- ORL - Endoscopes used in ear, nose & throat  
Tristel free to select route to market

**Parker**

Manufacturer  
for Americas

# Tristel and Parker business model

## Parker manufacture

- Ultrasound (Parker sales channel): at cost
- Other clinical areas (Non-Parker sales channels): standard contract manufacturer margin

## Parker distribution - ultrasound

Tristel  
ULT  
HLD } Royalty = 24% of Parker net sales

Tristel  
DUO  
ILD } Royalty = 20% of Parker net sales

# USA - the technology landscape

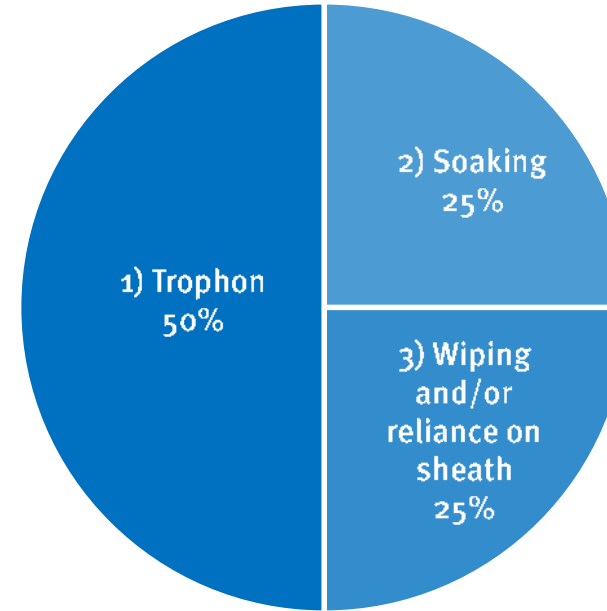
## Endocavity ultrasound probes: HLD

- Number of ultrasound scans in USA ~215M
- Number requiring HLD 20% ~43M

Illustrative segmentation



Nanosonics trophon®



Civco Astra VR

1. Nanosonics trophon® - nebulized hydrogen peroxide used in a machine (installed base 31.12.22 = 27,240 units)
2. Various chemistries which are FDA approved for HLD - peracetic acid and aldehydes - used in machines and baths (e.g. Civco Astra VR)
3. Wipes typically quaternary ammonium compounds, not approved for HLD and/or reliance on a probe cover (sheath)

# USA - the technology landscape

## Skin surface ultrasound transducers: ILD or LLD

- Number of ultrasound scans in USA ~215M
- Number requiring ILD/LLD ~172M

### Wiping:

Quaternary ammonium compounds, bleach, hydrogen peroxide



# Tristel's potential impact on the USA ultrasound market

---

## Emerging trends favour Tristel:

- Mobile ultrasound growing at 13.6% CAGR vs 5% for traditional ultrasound – mobile ultrasound requires mobile HLD.
- Growing number of skin surface scans, e.g. catheterisation for an aging population with increasing levels of obesity, are made easier if guided by skin surface ultrasound. Skin surface ultrasound would be categorised under Spaulding as requiring ILD/LLD, but skin puncture increases infection risk and HLD might be preferred if flexible and affordable. Tristel is mobile and easily deployable, avoiding capital investment.
- We expect to grow the number of all ultrasound procedures that elect HLD.

# Benchmarking against our key competitor: Rest of world

Tristel	Trophon
# ultrasound scans disinfected	# ultrasound scans disinfected
5.8M <sup>(1)</sup>	2.5M <sup>(2)</sup>

## Tristel advantages:

- Mobile – HLD to where ultrasound is needed
- Shorter contact time – 2 minutes vs 7 minutes plus
- No capital cost
- No breakdowns

(1) Company data

(2) Competitor data

# Product to market: timeline

Medical Device Disinfectants	Revenue model	FY23	FY24	FY25	FY26	FY27	FY28
<b>Tristel ULT - HLD ultrasound probes</b>							
USA	Royalty revenue - Parker channel						
Canada	Royalty revenue - Parker channel			H1 approval	H2 sale		
Other NA territories	Royalty revenue - Parker channel			H1 approval	H2 sale		
<b>Tristel OPH - HLD ophthalmic devices</b>							
Canada	Product sale via 3rd party distribution*						
USA	Product sale via 3rd party			H1 approval	H2 sale		
Other NA territories	Product sale via 3rd party						
<b>Tristel ORL - HLD ear-nose-throat devices</b>							
USA	Product sale via 3rd party						
Canada	Product sale via 3rd party						
Other NA territories	Product sale via 3rd party						
<b>Surfaces Disinfectants</b>							
USA Tristel JET - ILD	Product sale via 3rd party						
USA Cache	Product sale via 3rd party					EPA	States
Canada Cache	Product sale via 3rd party						

<b>KEY:</b>
Submission
Approval
Sale

\* Innova Medical Ophthalmics

# Ophthalmology

- Tonometers, pachymeters and lenses contact the cornea (mucosa) and require HLD



- **Tristel OPH approved by Canada Health as an HLD**
- Very few semi-critical ophthalmic devices in NA and ROW are HLD disinfected – they are soaked in sodium hypochlorite (Milton), alcohol and hydrogen peroxide
- **Tristel OPH launched at Canada's Infection Prevention Conference, May 2023**
- **Tristel OPH worldwide sales ~ £1M; worldwide procedures ~ 1.5M**



# Tristel Inc. Board

---

Paul Swinney, President

Julija Shabanova, CEO

Liz Dixon, CFO

Mika Nishimura, NED

# Biographies

## Julija Shabanova

Julija has worked at Tristel for 18 years. Julija has spearheaded the North American regulatory and business development project since its inception in 2015. Alongside the North American initiative, Julija is an executive director of Tristel Solutions (the principal subsidiary of the Group), responsible for the Group's international distributor network.



## Mika Nishimura

Mika is a USA resident. She has an exceptional track record of leading businesses from inception to scale across different healthcare clinical segments, including cardiovascular, fertility and oncology. Mika is an independent director of Si Bone (NASDAQ – SIBN), an orthopaedic/spine implant company; Accuray (NASDAQ – ARAY), a radiation oncology equipment manufacturer; and HOYA (Tokyo Stock Exchange Prime: 7741), a diversified manufacturer of life science and IT products.



# Tristel Inc. will operate from Massachusetts



# North America operational model – Infrastructure “LITE”

---

## Our roles:

- Master distributors (Parkers & Innova) – liaison; education & training; strategic marcomms; KOL development; joint conferencing
- Sub-distributors (GPOs; hospital groups; regional distributors; manufacturer’s reps) – education & training; key account support
- Digital traceability – 3T support

## Year 1:

- People: 2-3 headcount transferred to NA from Group
- Recruitment: strategic marketing & regulatory
- Opex budget: FY24 £350,000



---

Thank you