# **TSTL** 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

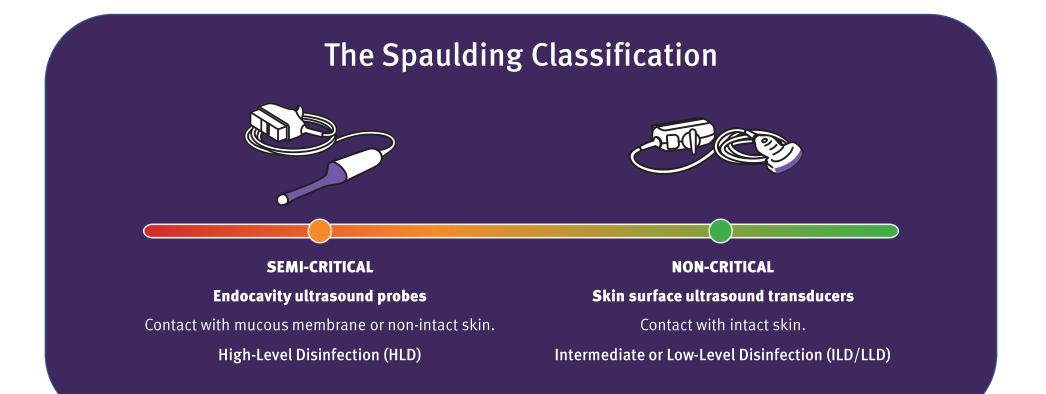


### Ultrasound technology





### Segmenting the ultrasound market





North America Business Plan 4 of 19

# The regulatory agencies

#### Shaping our marketing and brand strategy



HIGH LEVEL DISINFECTION Endocavity probes, and skin surface transducers that may contact non-intact skin during use FDA 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

ULTRASOUN

WATER SOLUBLE

PARKER

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





Traditional console and mobile ultrasound <sup>(1,2)</sup>

Parker Ultrasound Gel and Probe Covers



1) 215,000,000 ultrasound scans in US (Company estimate)

2) 271,000 traditional ultrasound consoles in US (Competitor data)



# **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

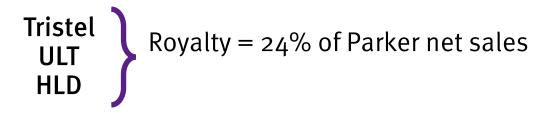


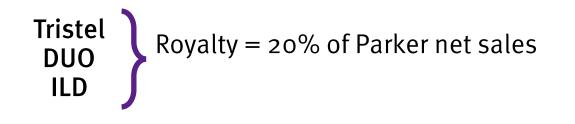
# **Tristel and Parker business model**

#### Parker manufacture

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

#### Parker distribution - ultrasound



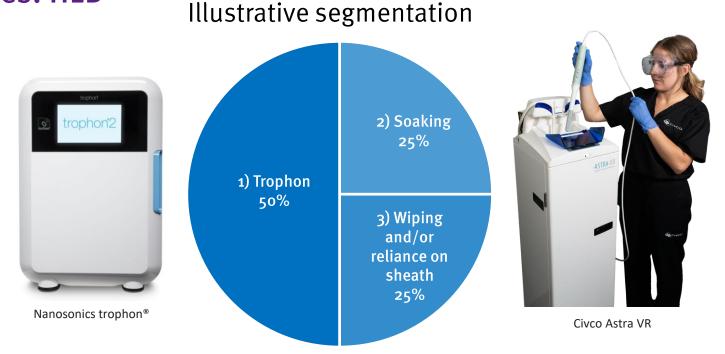




# USA - the technology landscape

#### Endocavity ultrasound probes: HLD

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



- 1. Nanosonics trophon<sup>®</sup> 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
	Tristel	ULT - HLD ultra	sound probes	-		-		
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			
	Tristel	OPH - HLD opht	halmic devices					
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							
	Tristel OF	RL - HLD ear-no:	se-throat devices	5				
USA	Product sale via 3rd party							
Canada	Product sale via 3rd party							
Other NA territories	Product sale via 3rd party							
	•	Surfaces Disin	fectants					
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							

KEY: 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 ~  $\pm 1M$ ; worldwide procedures ~ 1.5M



### Tristel Inc. Board

Paul Swinney, President Julija Shabanova, CEO Liz Dixon, CFO Mika Nishimura, NED



North America Business Plan 16 of 19

#### North America Business Plan 17 of 19



manufacturer of life science and IT products.

# **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



#### Tristel Inc. will operate from Massachusetts



North America Business Plan 18 of 19

### 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