

XVIVO

Investor presentation

Autumn, 2021



Today's presenters

A portrait of Dag Andersson, an older man with short grey hair and glasses, wearing a dark blue suit jacket over a white shirt. He is standing with his arms crossed against a light grey background.

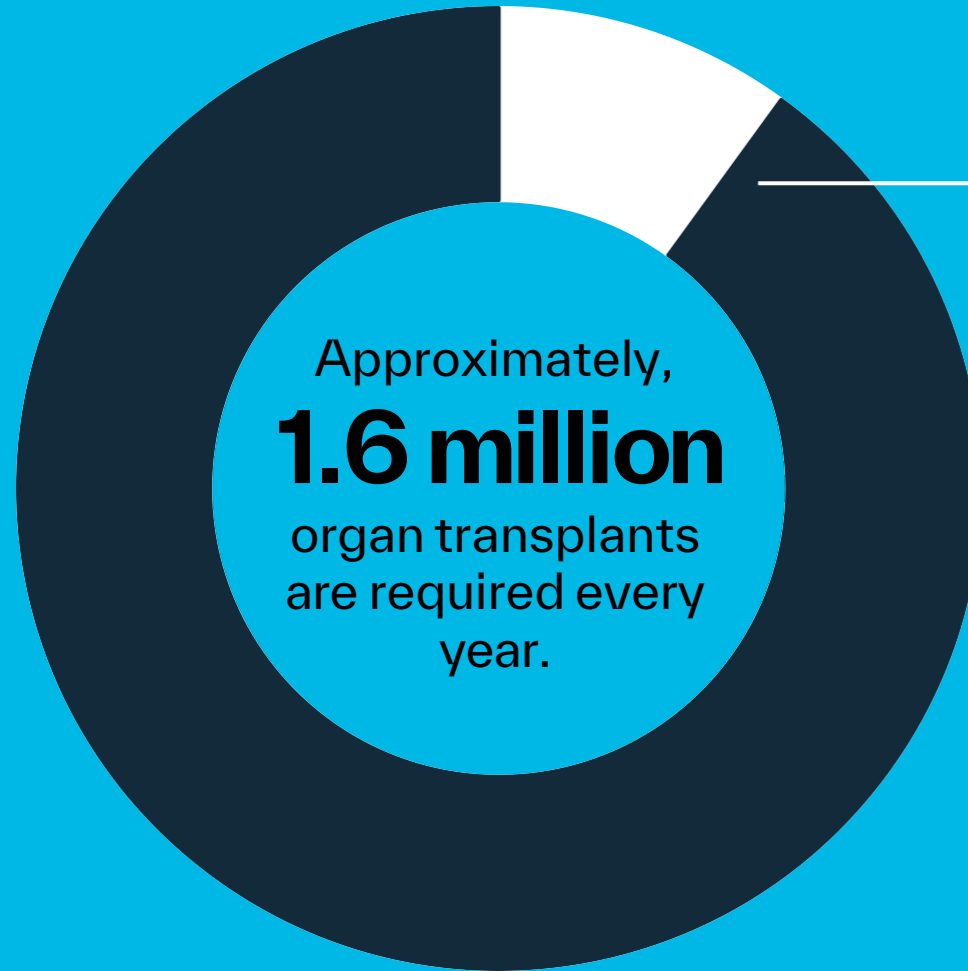
Dag Andersson CEO

A portrait of Kristoffer Nordström, a younger man with dark hair and blue eyes, wearing a dark suit jacket over a white shirt. He is standing with his arms crossed against a light grey background.

Kristoffer Nordström CFO

Market and trends

The need



Approximately,
1.6 million
organ transplants
are required every
year.

With only

160,000

organ transplants
performed globally
each year, this only
covers

**10% of the
total need.**

The transplant market today*

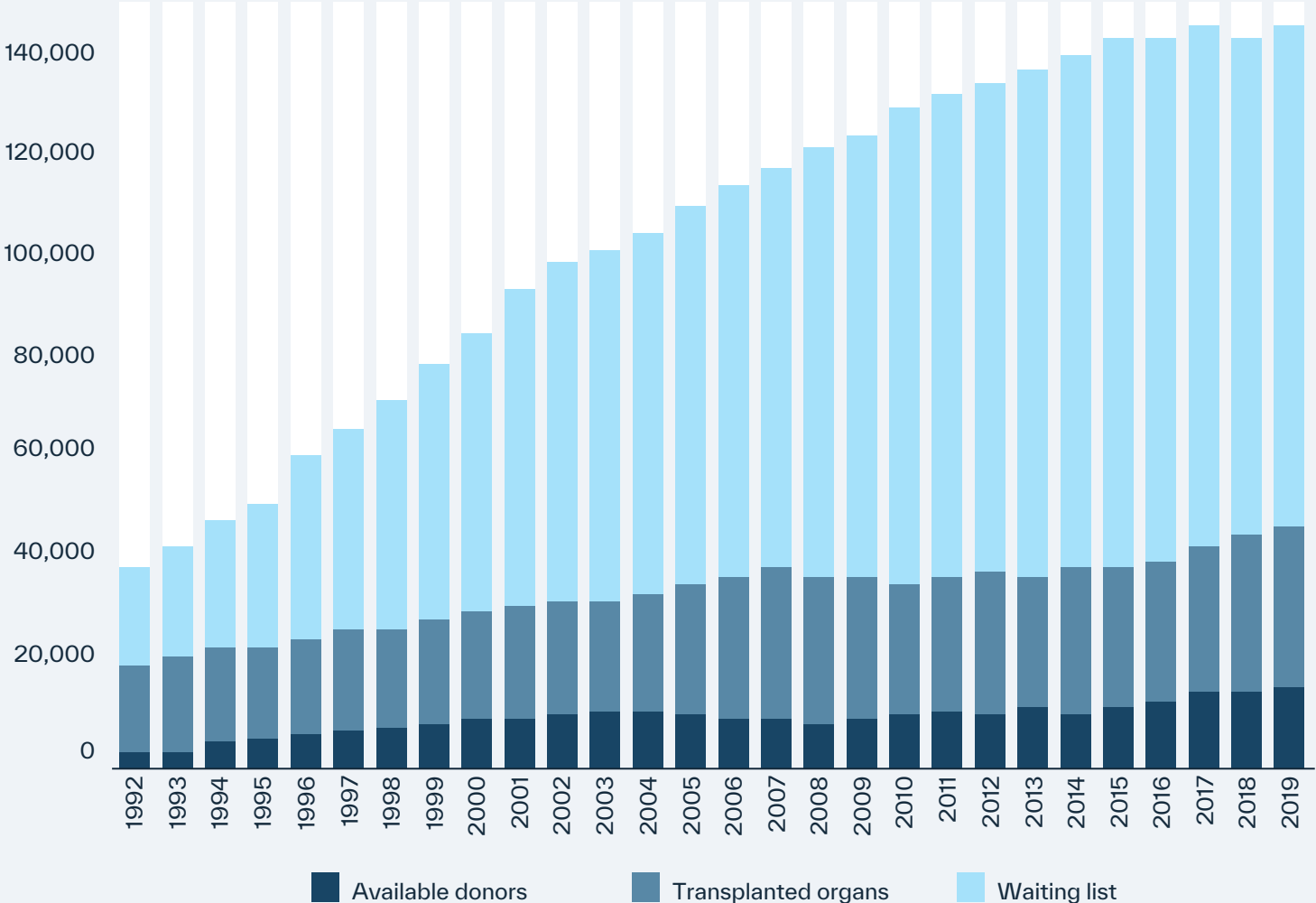
**A \$1bn
market**

	Lung	Heart	Liver	Kidney
No of Tx	6.700	8.600	28.000	62.000**
Americas	41 %	42 %	30 %	34 %
Europe	35 %	34 %	32 %	32 %
RoW	24%	24%	38%	34%
Active clinics	250	350	1.000	2.200

* Solid organs from deceased donors, 2019 figures

** 98.000 including donations from living donors

The trend (a US example)



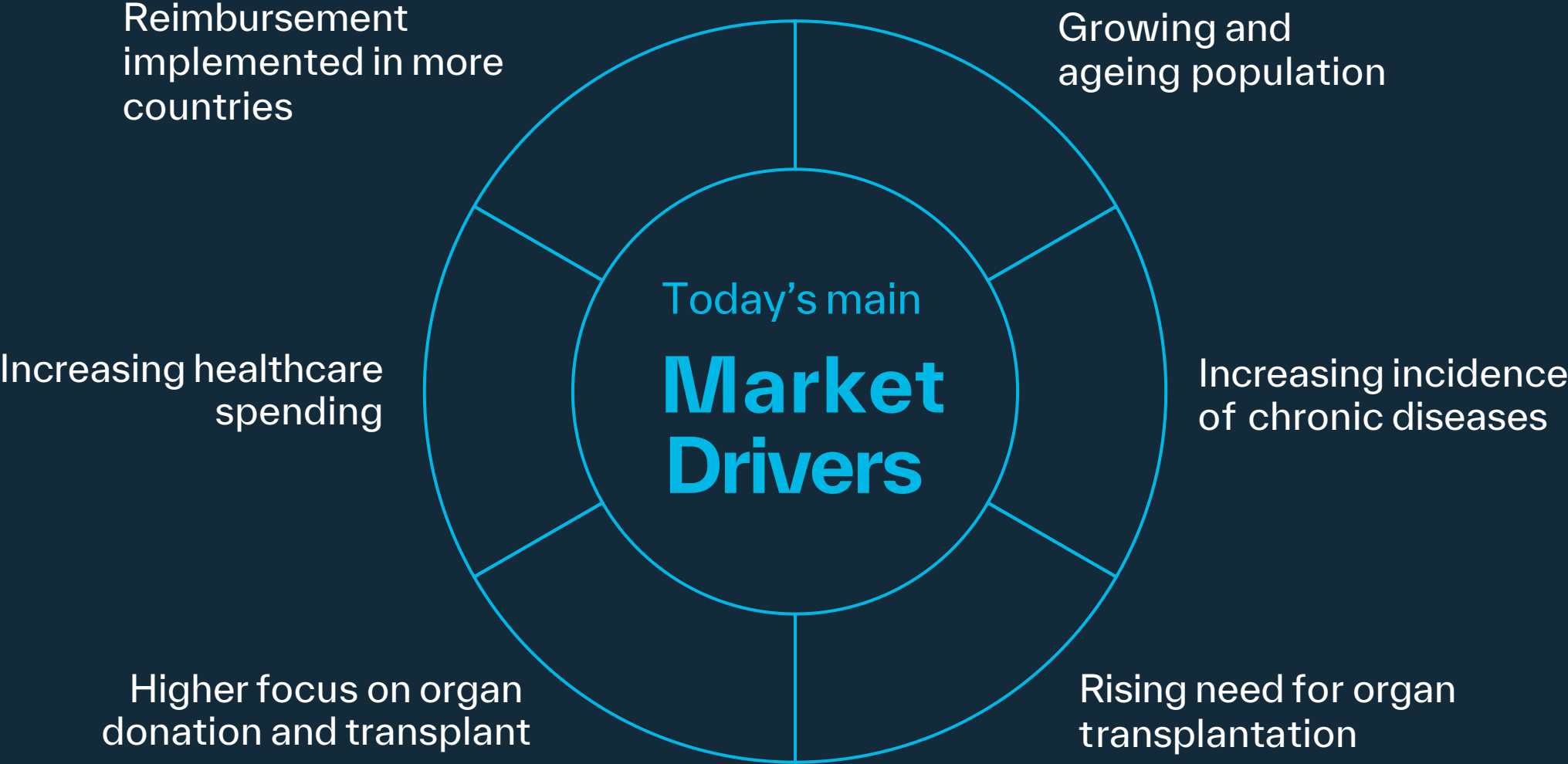
It is estimated that approximately

150,000 patients

in the United States are currently **waiting for a new organ.**

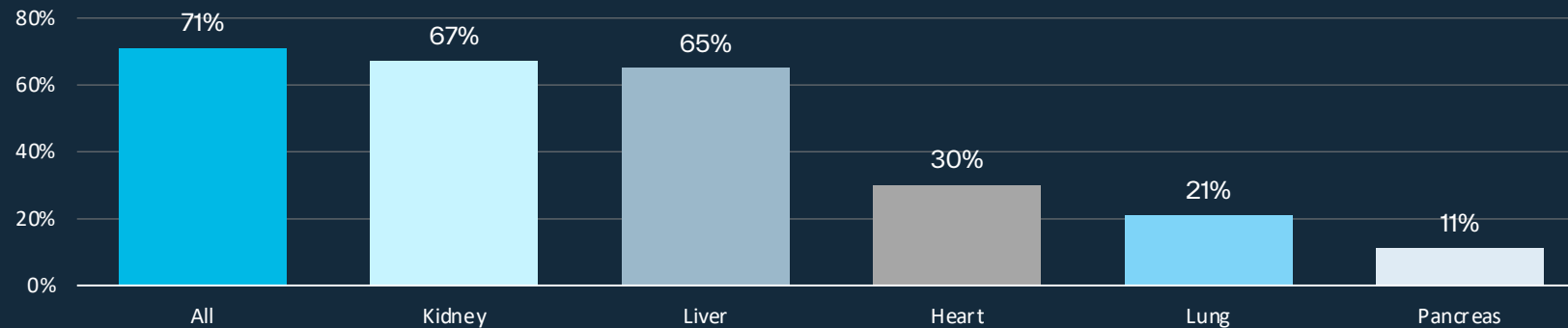
Approximately **25%** of patients waiting for new lungs or heart **die while waiting for a new organ.**

Market drivers



Key issues in organ donation

Utilization rate (%)



4 of 5 donated lungs and **1 in 3** kidneys and livers are **discarded**

Shortage of supply of donated organs.

Low utilization of donated organs from **DBD¹** donors.

Low or no use of **DCD²** donors in thoracic transplantation.

Deterioration of organs after retrieval until implant surgery.

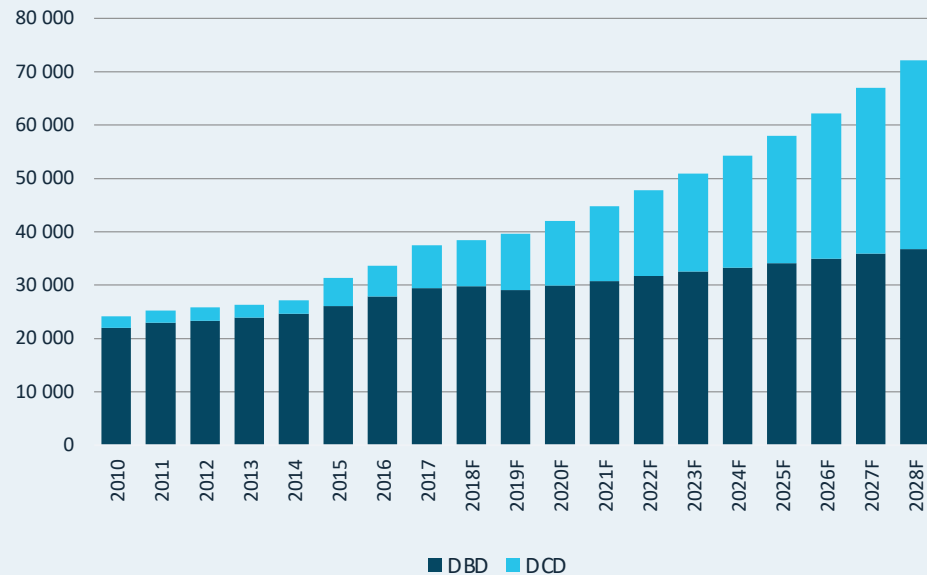
¹ DBD - Donated after Brain Death

² DCD - Donated after Circulatory Death

Donation trends support increased usage of machine perfusion

An increased DCD portion expected to lead to an increased need of machine perfusion and warm evaluation of donated organs

Source of donation development
(2010 - 2028F)



Main trends estimated until 2028:

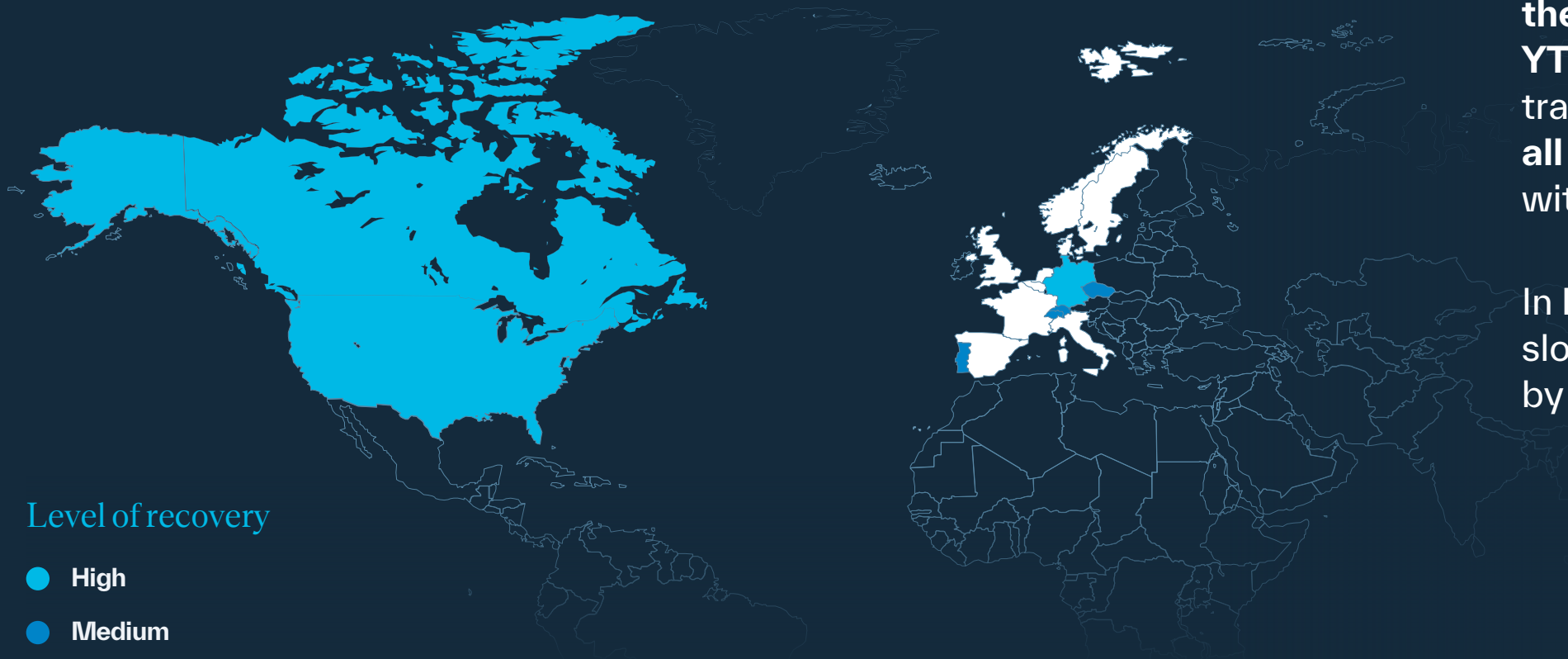
- DBD estimated growth: **+3%** p.a.
- DCD estimated growth: **+14%** p.a.

DCD portion of **50%** in 2028F

Transplant activity

Covid-19

Transplant activity overview



Level of recovery

- High
- Medium
- Low

In the **US**, the market with the strongest recovery YTD, the number of transplants increased for **all** major organs compared with 2020 and 2019

In **Europe**, recovery is slower and **varies** country by country

Example of level of recovery - lungs

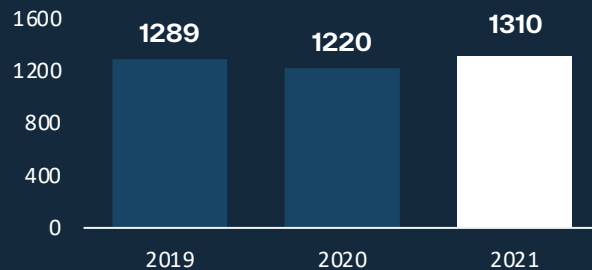
Lung transplants

U.S.

Level of recovery

- No of LTx: **High**
- Machine perfusion (EVLP): **Medium/high**

Number of transplants (U.S.)



Europe/RoW

Level of Recovery

- No of LTx: **Medium/Low**
- Machine perfusion (EVLP): **Low/medium**



XVIVO's offering

The first all-organ company

1.

First global all-organ company

Through the acquisition of Organ Assist, XVIVO delivers advanced solutions for transplantation of all organs

2.

World leading in Lung and Liver transplantation with established network in thoracic and abdominal surgery

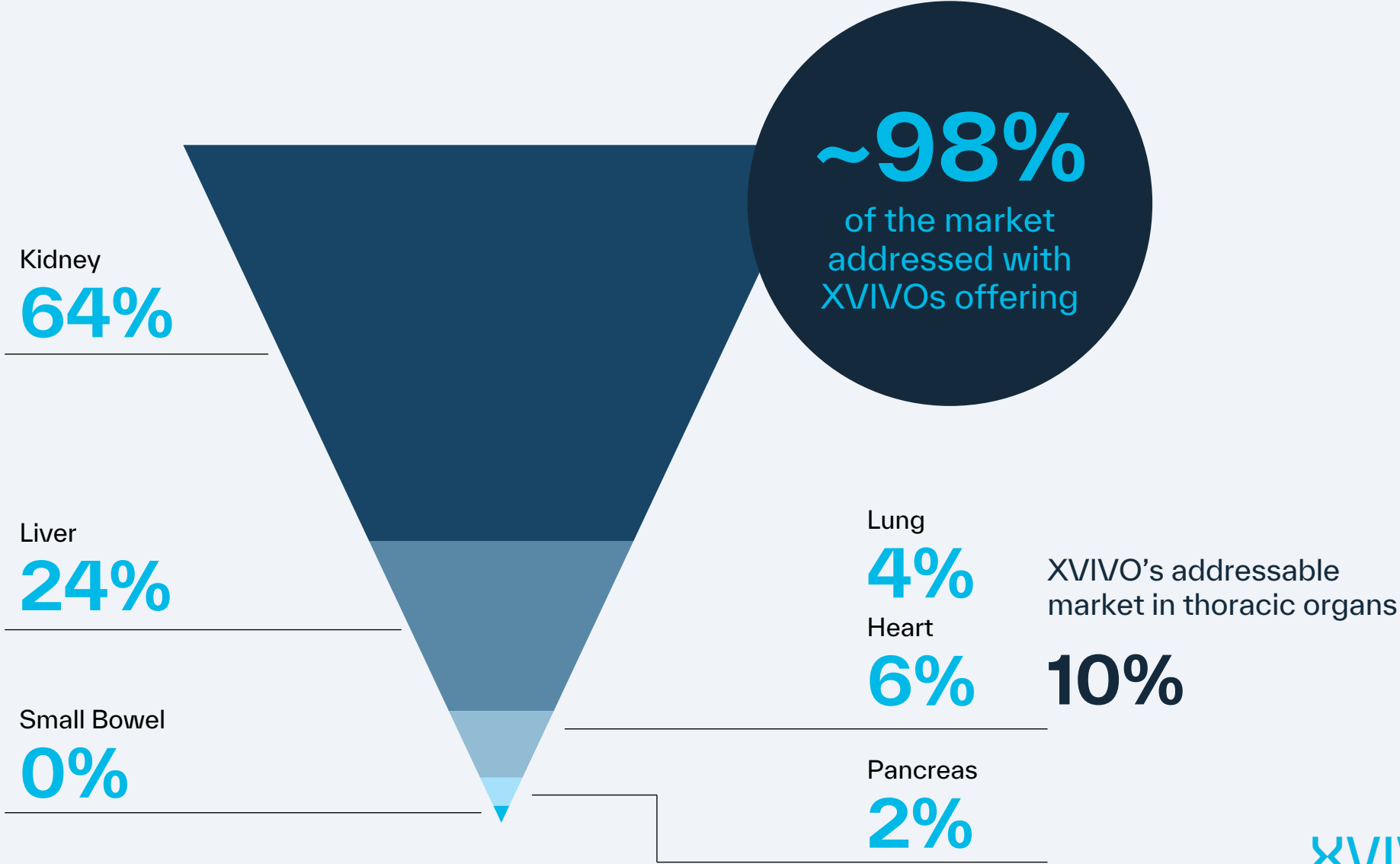
XVIVO is a strong global brand and market leader in liver and lung transplantation

3.

Experts in advanced solutions for transplantation

Together with world leading key opinion leaders in the transplantation field, we develop the optimal solutions for utilizing more organs for transplant

Addressing ~98% of the market



The XVIVO Product Range

Lungs

Machine perfusion platforms



XPS™



LUNG ASSIST



XVIVO LS™

Disposables for machine perfusion



XPS DISPOSABLE LUNG KIT™



STEEN SOLUTION™

Static preservation



PERFADEX PLUS®



XVIVO SILICONE TUBING SET

Heart



XVIVO HEART DEVICE



XVIVO DISPOSABLE HEART SET™

* Product developed and entering regulatory phase

Kidney



KIDNEY ASSIST TRANSPORT™



KIDNEY ASSIST™

Liver



LIVER ASSIST™




DONOR ASSIST™

Our global presence

Direct sales
to approximately
40 countries
globally.

Distributor model used in
markets outside North
America, Europe and Oceania.



 XVIVO Perfusion
office/subsidiary

XVIVO

Recent highlights

Interesting findings in the Lancet study (Nov 20)

Multicentre study COPE Consortium

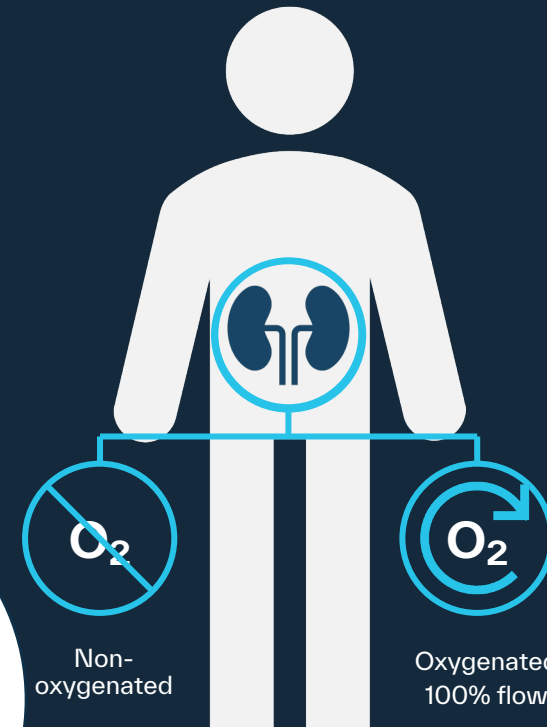


The group treated with **100% oxygen** showed significant better results compared to the control group:

- Complete loss of graft function reduced from **10% to 3%**
- Reduced acute rejection with **48%**
- Significantly improved renal function

Authors suggests that using **100% oxygen** with full flow will **reduce**;

- Severe complications
- Additional diagnostic procedures
- Hospital re-admission
- Costs for chronic dialysis



- Double blinded
- Computer- randomized study
- 106 kidney pairs included

- Donor >50 years
- Donated after Circulatory Death (DCD) III (high risk donors)
- Kidney pair were its own control group

Important milestone within abdominal transplantation

- In May 2021, XVIVO announced its submission of a **510(k)** file with US FDA for **Kidney Assist Transport**
- The goal is to receive market clearance in the US by end Q3
- The Kidney Assist Transport is XVIVO's transportable organ preservation system designed for kidneys
- The submission is an important milestone for XVIVO towards establishing a commercial presence within abdominal transplantation in the US

Q3 Focus areas

- Finalize US go to market strategy
- Initiate customer pre-launch activities
- Training and education
- Secure optimized manufacturing and supply chain

Target: US launch in the beginning of Q4 2021



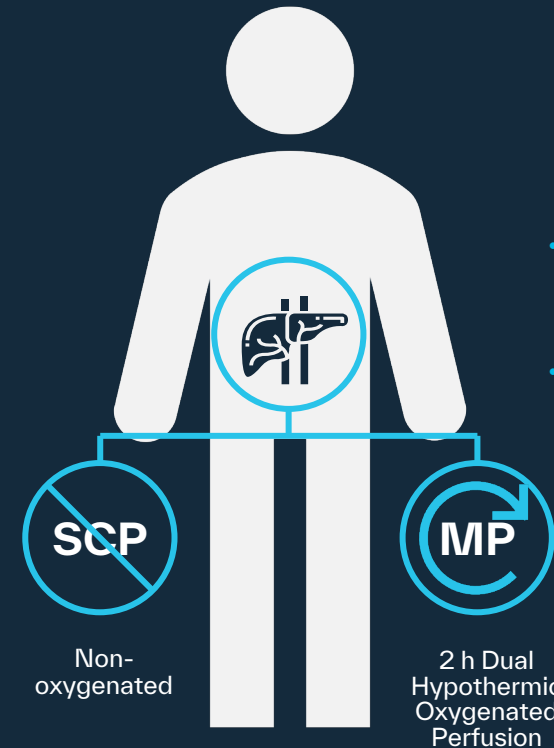
Key findings in DHOPE-DCD trial (Feb 21)

Multicentre study in 6 European centres



The study by van Rijn et al, in which Liver Assist was used, demonstrates that **2 hours of DHOPE** (Dual Hypothermic Oxygenated Perfusion) leads to;

- **2/3** lower rates of biliary complications
- Less hemodynamic compromise
- Incidence of early graft dysfunction reduced by **~50%**



- Adults undergoing transplantation of a liver donated after Circulatory Death (DCD III)
- Randomized to either DHOPE or SCP

Progress in clinical trials

European Heart preservation trial

5 centers are currently including patients:

- Sahlgrenska University Hospital (Gothenburg, SE)
- University Hospitals Leuven (Leuven, BE)
- Hospital Puerto de Hierro (Madrid, ES)
- La Pitié Salpêtrière (Paris, FR)
- *One not published (DE)*

Next up: German, Austrian and an Italian centre

In Q2, 4 new, prominent centers showed interest in the trial. For these centers, the application process has started.

Timeline: Last patient in Q4 2022
/ Commercial launch Q1 2024

PrimECC

1 site is currently including patients, Sahlgrenska Hospital, SE

- Ethics committee applications submitted to Rikshospitalet in Oslo, NO and Rigshospitalet in Copenhagen, DK.
- Discussions have also been initiated with two German high volume centers.

Timeline: Clinical data submission (MDR) in Q2 2023

AOPO 50k transplants by 2026 Campaign

The Association of Organ Procurement Organizations (AOPO) **commits to achieving 50,000 annual transplants by 2026**. AOPO and its members will work with key stakeholders to implement a series of initiatives:

1. **Expand Collaboration** across the AOPO membership and among all stakeholders
2. **Reduce Health Inequities** to improve accessibility of organ transplants in minority communities
3. **Maximize Organ Utilization** by transplant programs
4. **Drive Innovation** to increase donation and maximize transplantation



The graphic features a dark blue background with a white silhouette of a human torso showing internal organs. To the right, the number '50,000' is written in large, bold, light green font. Below it, the text 'ORGAN TRANSPLANTS BY 2026' is displayed in white, with 'BY 2026' in a smaller font. A white arrow points upwards and to the right, passing through the number. Below the main text, the tagline 'Saving and improving lives through organ, eye, and tissue donation' is written in small white font. At the bottom, there is a purple banner with the AOPO logo on the left and the text 'PARTNER WITH AOPO TO SAVE MORE LIVES' and 'WWW.AOPO.ORG/50K-TRANSPLANTS' on the right.

50,000 ORGAN TRANSPLANTS BY 2026

Saving and improving lives through organ, eye, and tissue donation

AOPO
ASSOCIATION OF ORGAN
PROCUREMENT ORGANIZATIONS

PARTNER WITH AOPO TO SAVE MORE LIVES
WWW.AOPO.ORG/50K-TRANSPLANTS

In alignment with our mission to lead the nation's organ donation community to save more lives, the Association of Organ Procurement Organizations (AOPO) commits to achieving 50,000 organ transplants annually by 2026. AOPO and its members will work with key stakeholders toward our collective vision to pursue the day when every donation opportunity results in lives saved by implementing a series of initiatives:

NICE gives support for EVLP (UK)

In May, XVIVO announced that The National Institute for Health and Care Excellence (NICE), has issued interventional procedure guidance recommending the use of Ex Vivo Lung Perfusion (EVLP) for preservation of lungs

Completed in Q2

- Guidelines published on Website (May)
- Perfadex Plus UK tender awarded (June)

Next steps

- XVIVO has initiated a process for reimbursement based on NICE guidelines
- Collation of clinical evidence on EVLP in UK
- Business case to be submitted to NHSBT
- Estimated reimbursement Q1 2023

Aug 2021



Regional EVLP commences

Jan 2022



EVLPs completed

Sept 2022



Collation of Clinical Data Preparation & Submission of Business Case

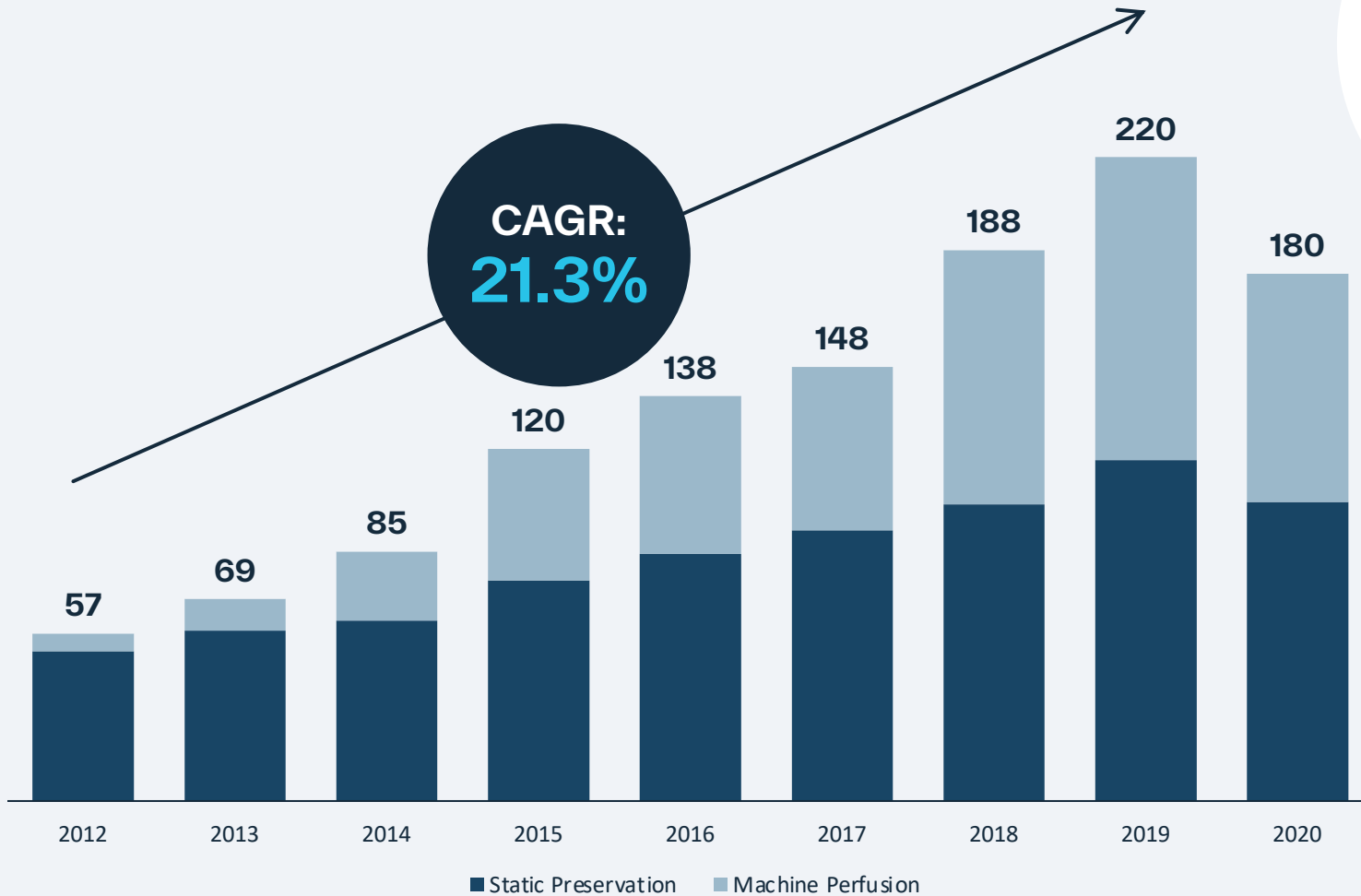
Q1 2023



Estimated Reimbursement Outcome

Financial Performance

Strong double-digit growth



COVID-19 pandemic impact on sales and product mix

- **Static preservation** has historically grown with the market.
- **Machine perfusion** has shown a **CAGR of 42 %** until 2019.

Net sales and results in Q2

SEK Thousands	Apr-Jun 2021	Apr-Jun 2020	Change	YTD
Net sales	59,263	30,393	95%	117,588
Gross income	44,547	23,102	93%	87,227
Gross margin, %	75	76		74
Operating income	-9,350	-12,709	-26%	-6,167
EBITDA (Operating income before depreciation and amortization)	-1,533	-5,452	-72%	9,674
EBITDA, %	-3	-18		8
EBITDA (adjusted) ¹	8,402	-954	981%	14,670
EBITDA (adjusted) ¹ , %	14	-3		12
Earnings per share ² , SEK	-0.31	-0.60	-48%	-0.10

¹ Adjusted for effect from costs attributable to cash-based incentive program for employees outside Sweden, integration costs as well as costs associated with the M&A activities. Adjusted amount net for the quarter, amounts to SEK 9.9 (-4.5) million for. Adjusted amount net for the period amounted to SEK 5.0 (-2.0) million.

²After dilution

Thoracic – Q2 Highlights

Net Sales

SEK 50 million (30)

Local currency growth

+82 %

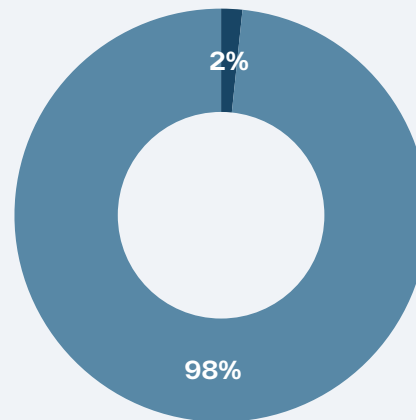
Gross margin

80 % (76)

Gross margin non-durable goods

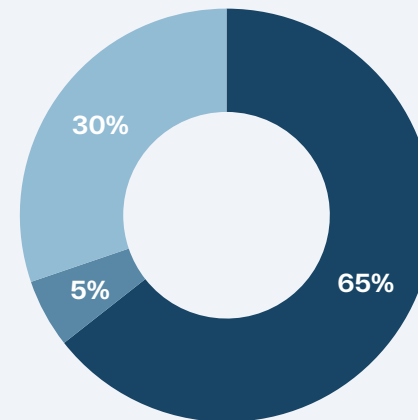
80% (81)

Net sales by segment (Q2)



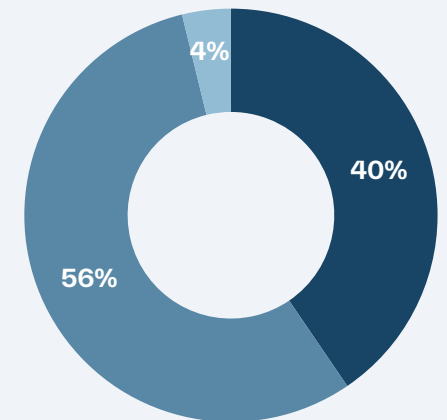
■ Durable goods
■ Non-durable goods

Net sales by region (Q2)



■ Americas ■ APAC
■ EMEA

Net sales by product category (Q2)



■ Machine perfusion ■ Static preservation
■ Other

Abdominal – Q2 Highlights

Net Sales SEK

9 million (-)

Local currency growth

+126 %

Gross margin

52 % (-)

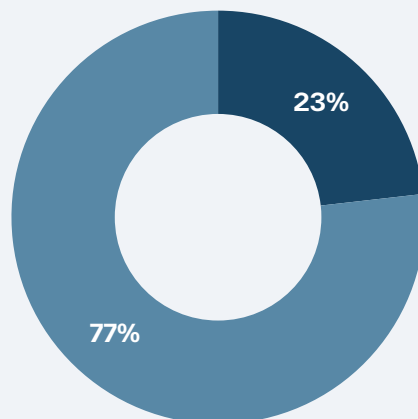
Non-durable goods

50% (-)

Durable goods

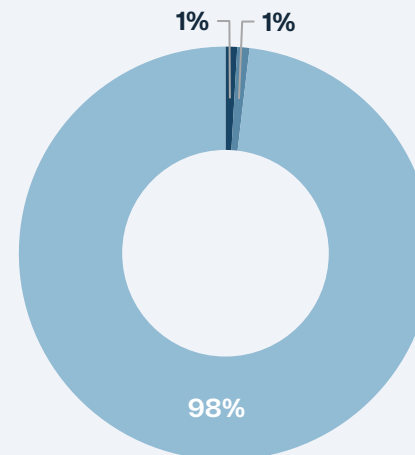
60% (-)

Net sales by segment (Q2)



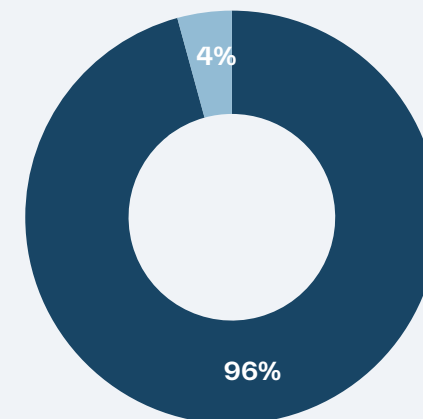
■ Durable goods
■ Non-durable goods

Net sales by region (Q2)



■ Americas ■ APAC
■ EMEA

Net sales by product category (Q2)



■ Machine perfusion ■ Static preservation
■ Other

Outlook 2021

Outlook 2021

Strategic Objectives for Q3-Q4

- Launch 2022-2026 strategic plan
- Launch Kidney Assist Transport in the US
- FDA submission for Liver Assist
- Speeding up the Heart Preservation and PrimECC clinical trials
- Increase reimbursement focus in Europe

XVIVO Capital Markets Day September 23

Save the date!

Location: GoCo Health Innovation City (Gothenburg)
and online webcast

Agenda: Market and trends, strategy and financials,
deep dives in our Thoracic and Abdominal business
areas, KOL interviews and Q&A

**Invitation will be distributed in August
through press release**

Our vision

Nobody should
die waiting for
a new organ
