Stichting
Trainingen
Infectie
Preventie

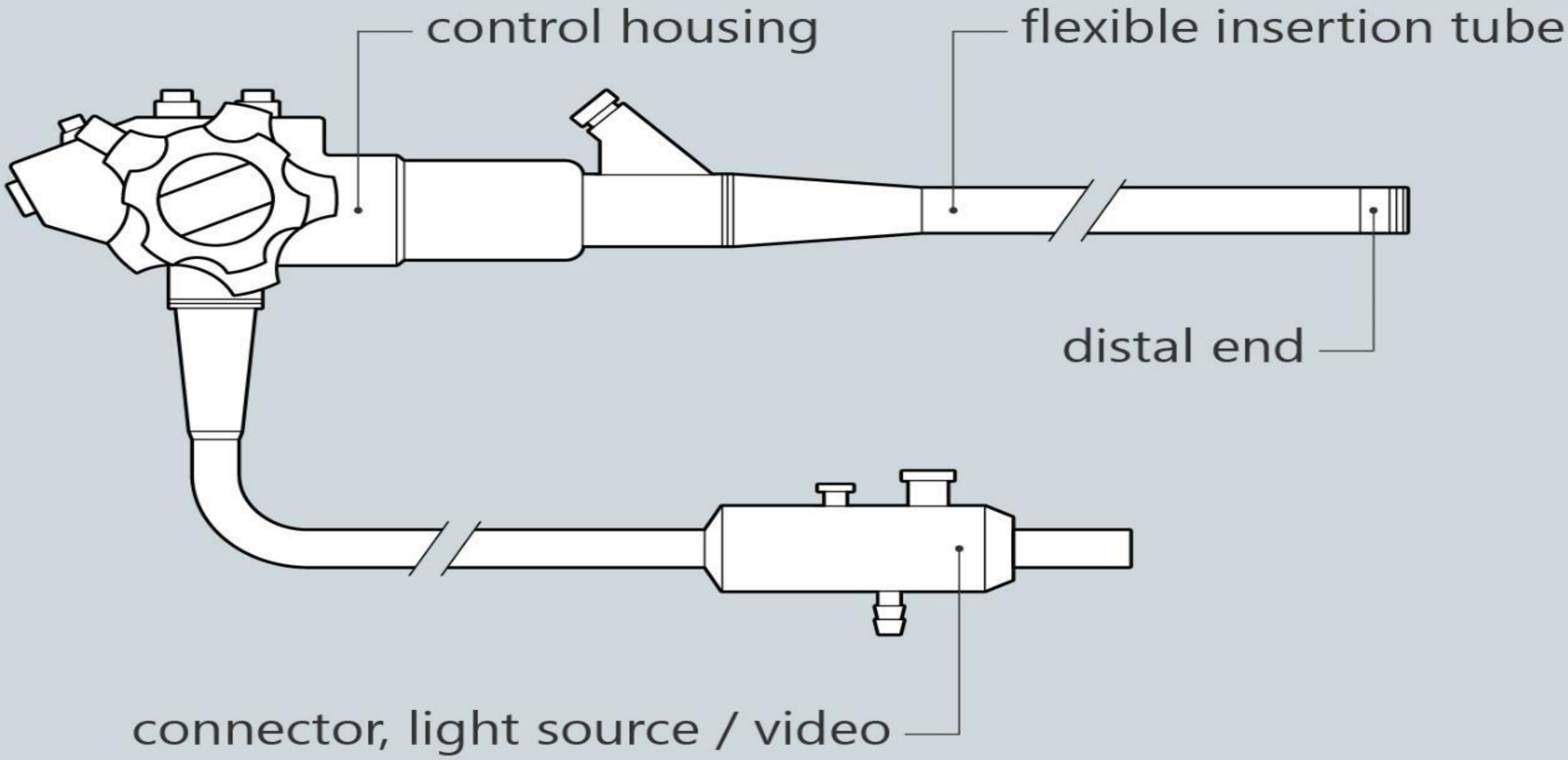
Disclosure slide

(potentiële) belangenverstrengeling	Fabrikant Endoscope Reprocessing solutions.
Voor bijeenkomst mogelijk relevante relaties met bedrijven	Wassenburg Medical
• Sponsoring of onderzoeksgeld • Honorarium of andere (financiële) vergoeding • Aandeelhouder • Andere relatie, namelijk …	Ronald Wassenburg President Wassenburg Medical b.v. Wassenburg Medical is part of the HOYA group and a sister company of Pentax – Medical.

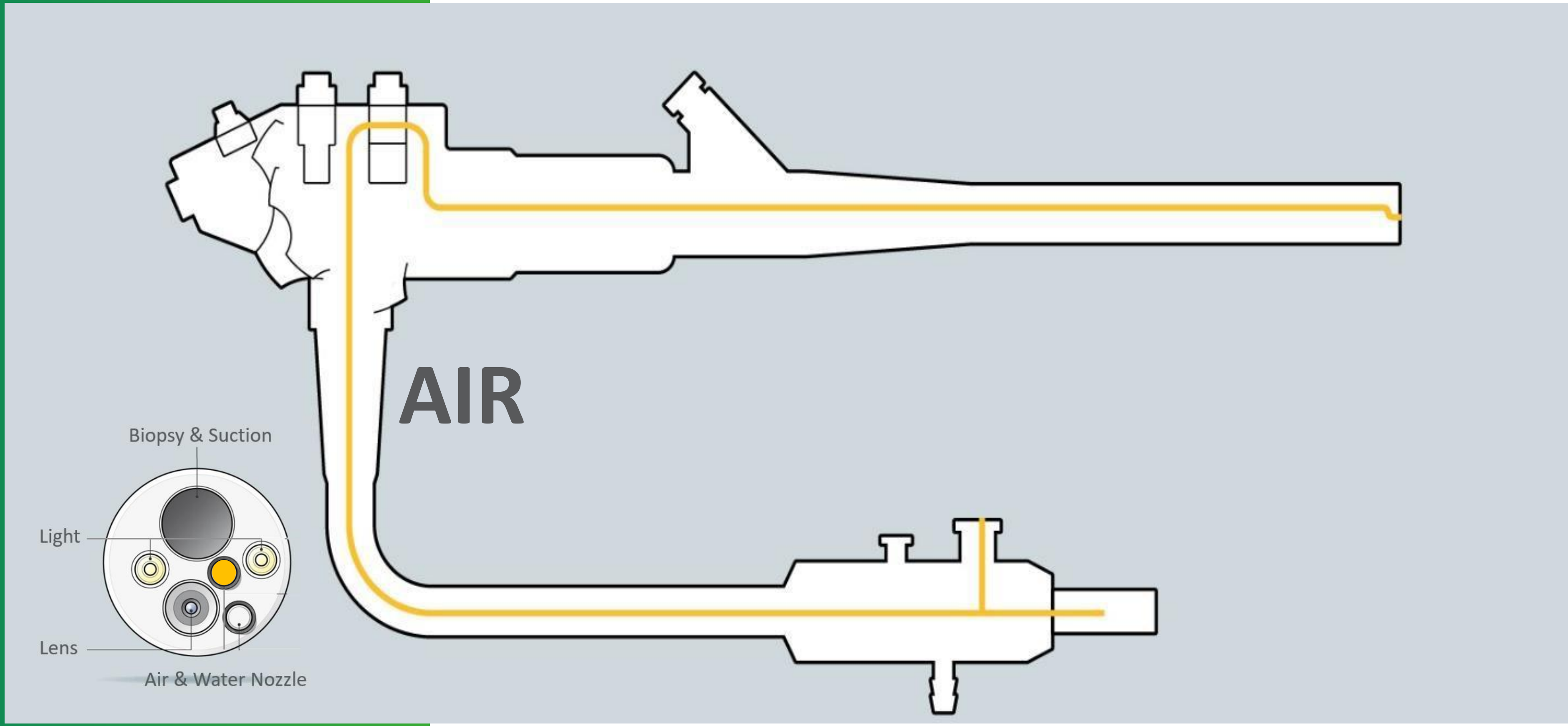
Where Flow Meets Pressure

The Challenge of Complex Endoscope Channels

THE ENDOSCOPE – THE CHANNELS

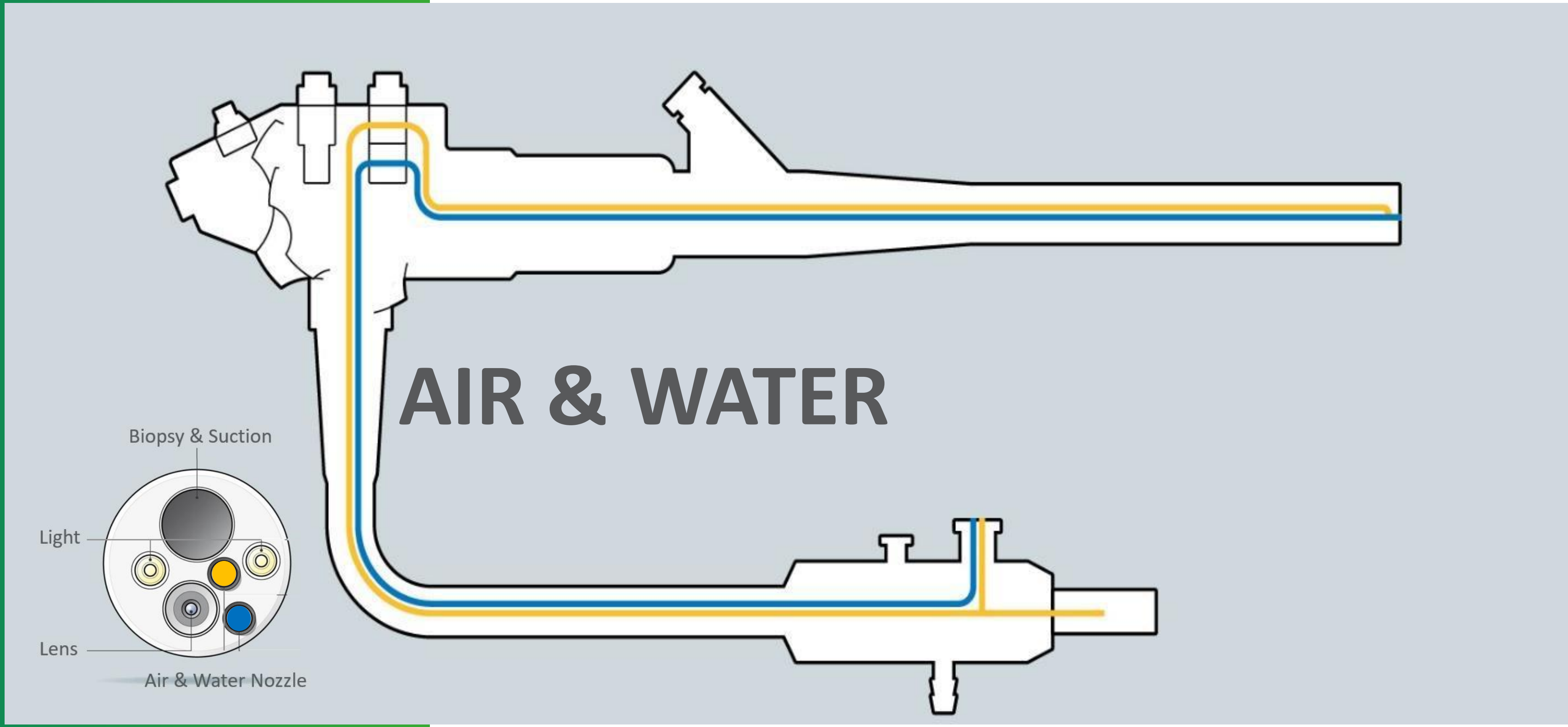

control housing
flexible insertion tube
distal end
connector, light source / video

THE ENDOSCOPE CHANNELS



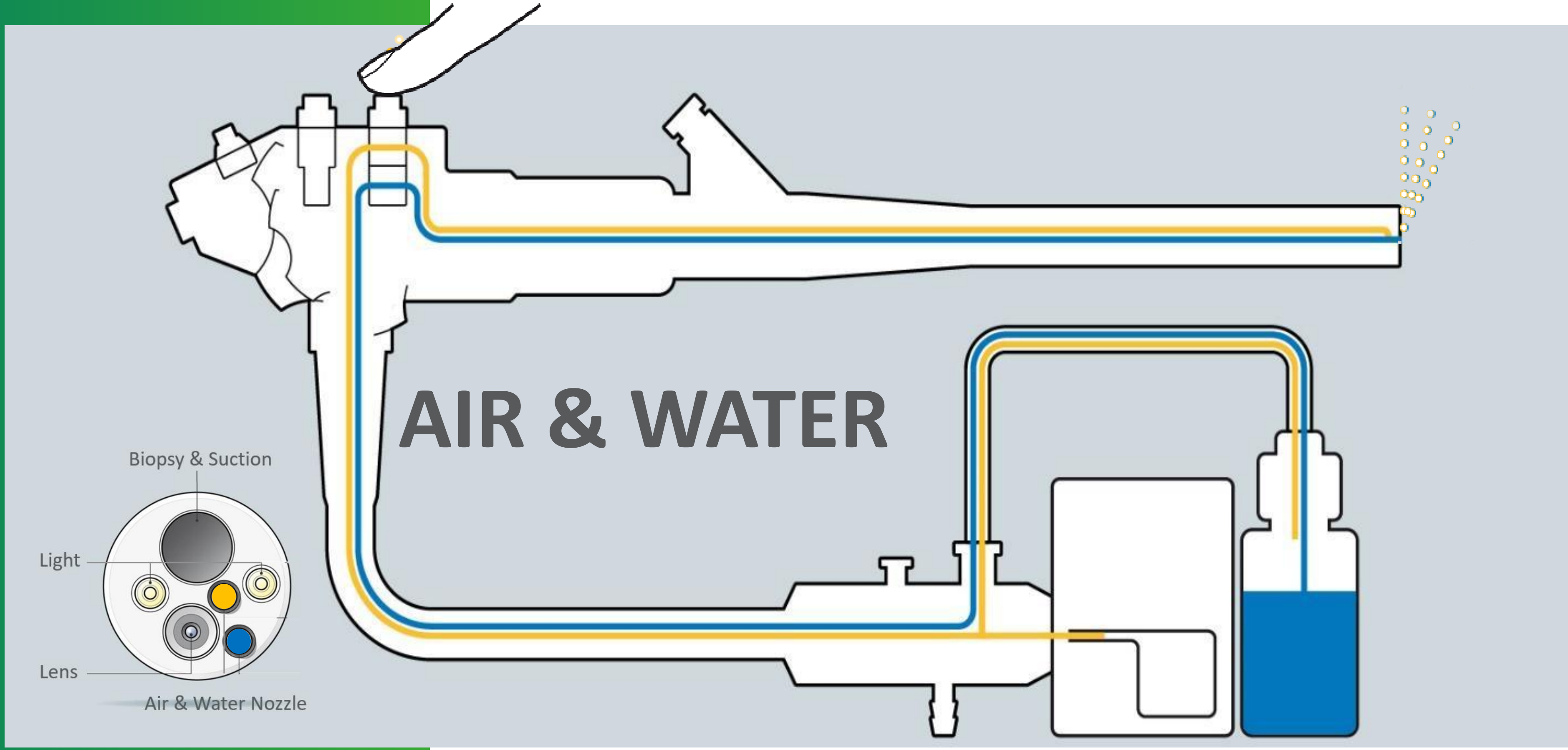
Gastroscope – Colonoscope - Duodenoscope

THE ENDOSCOPE CHANNELS



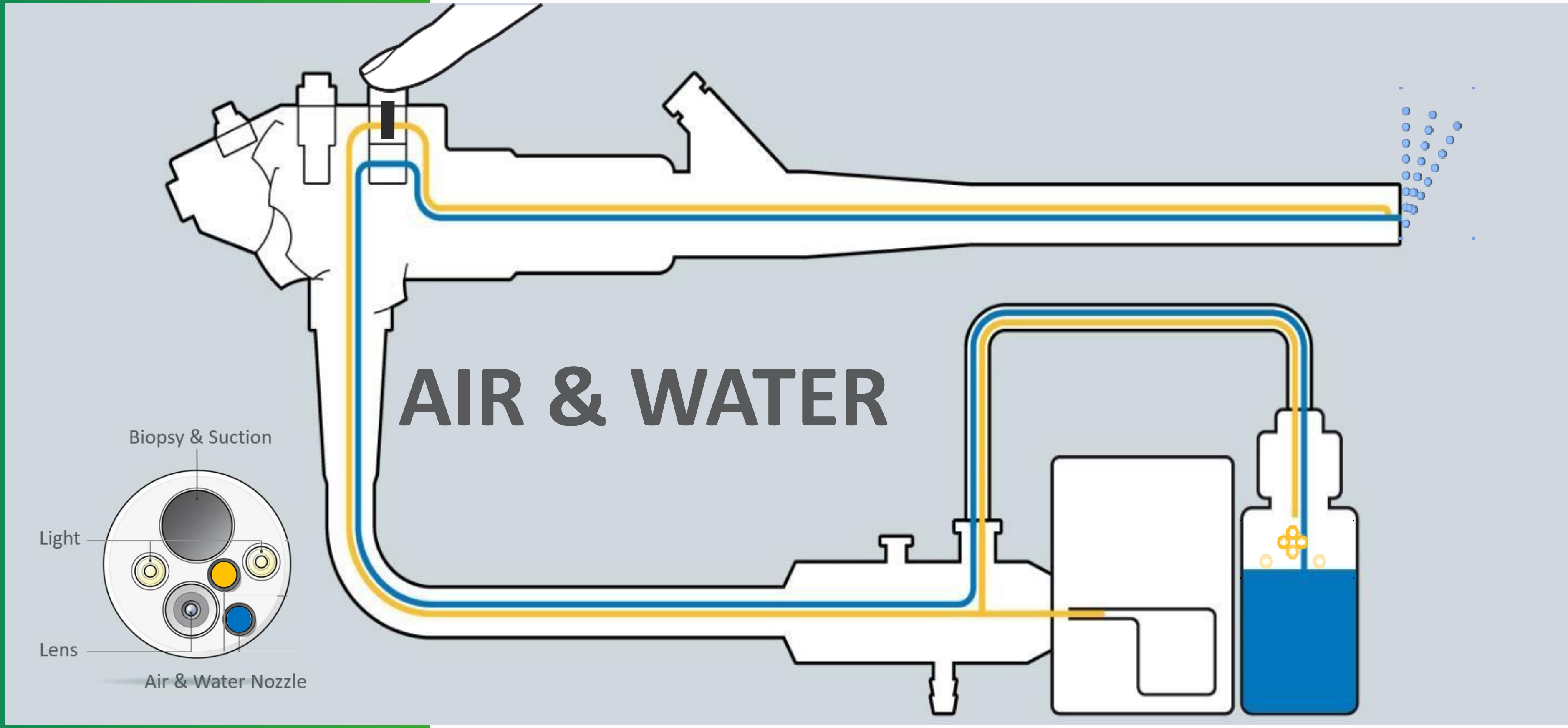
Gastroscope – Colonoscope - Duodenoscope

THE ENDOSCOPE CHANNELS



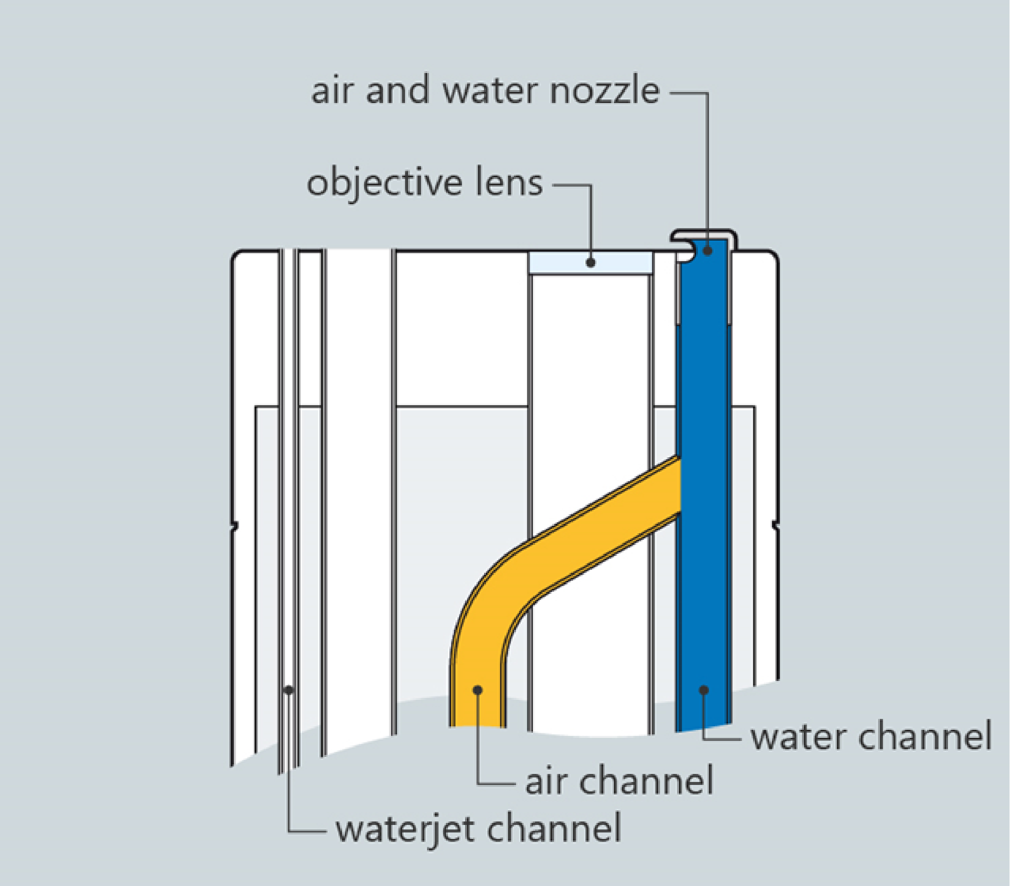
Gastroscope – Colonoscope - Duodenoscope

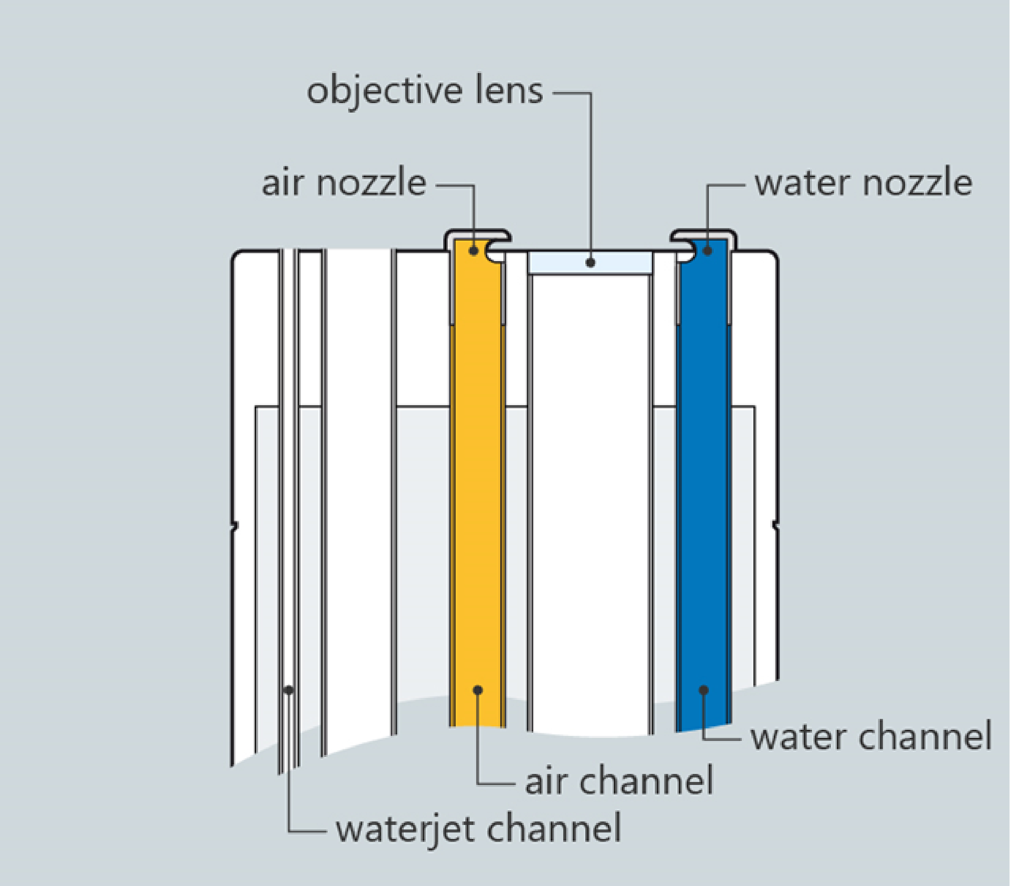
THE ENDOSCOPE CHANNELS



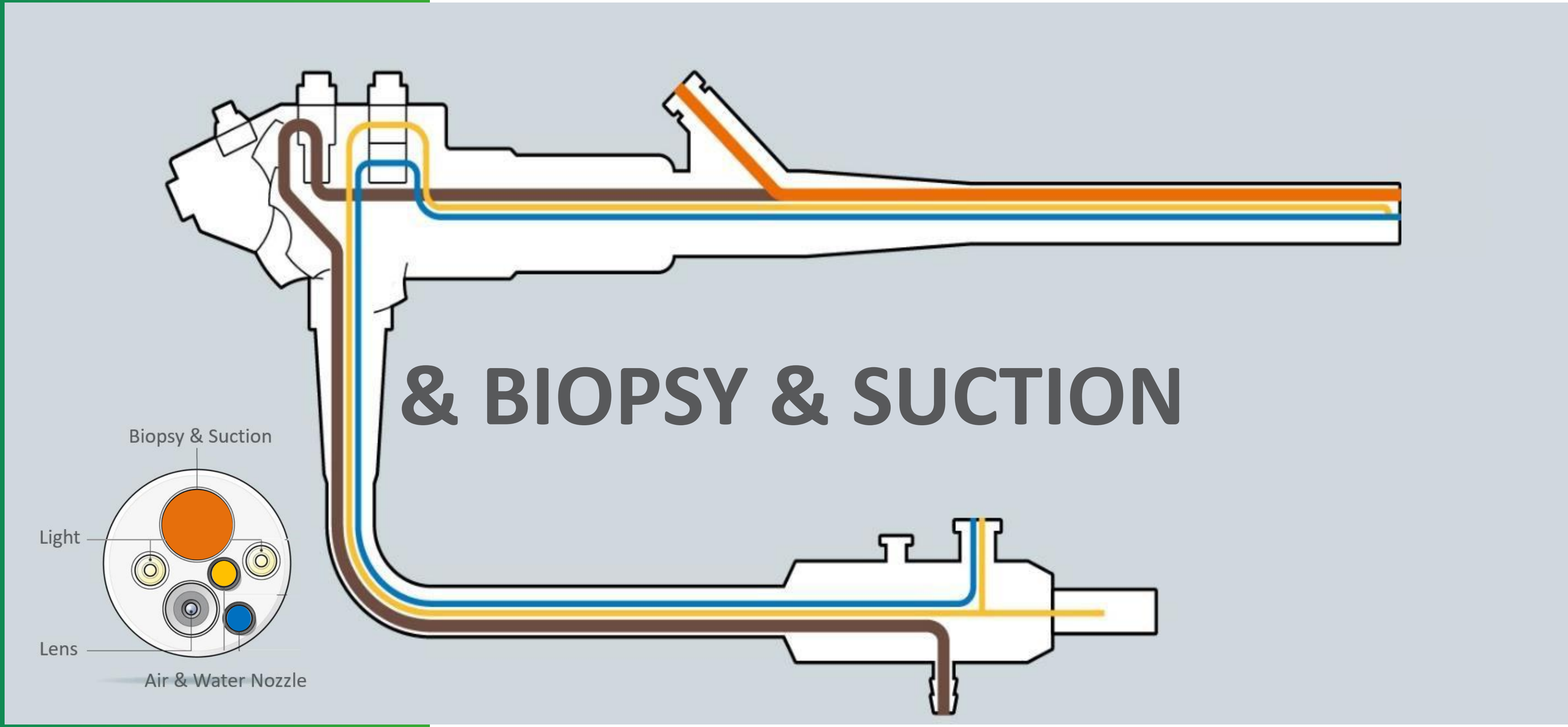
Gastroscope – Colonoscope - Duodenoscope

THE WATER AND AIR NOZZLE



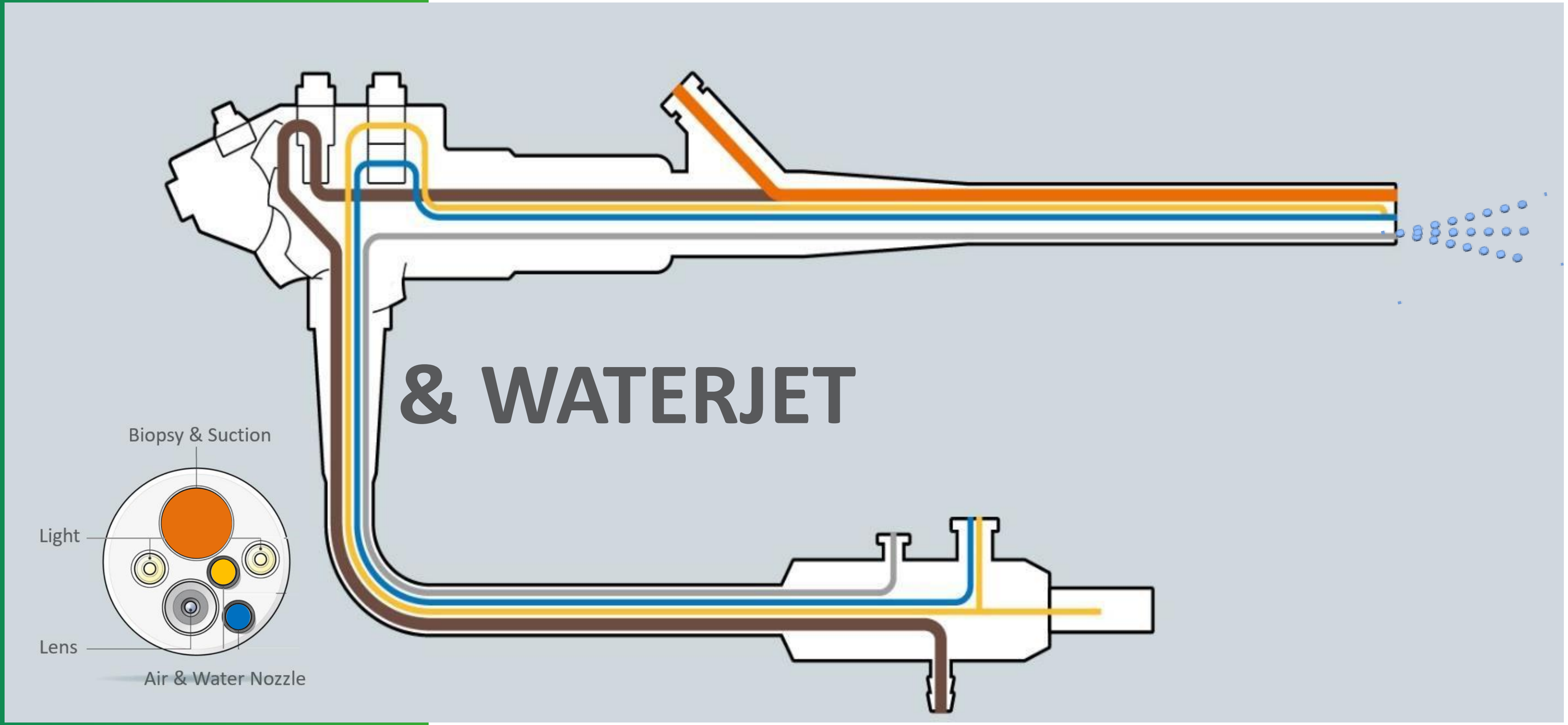


THE ENDOSCOPE CHANNELS



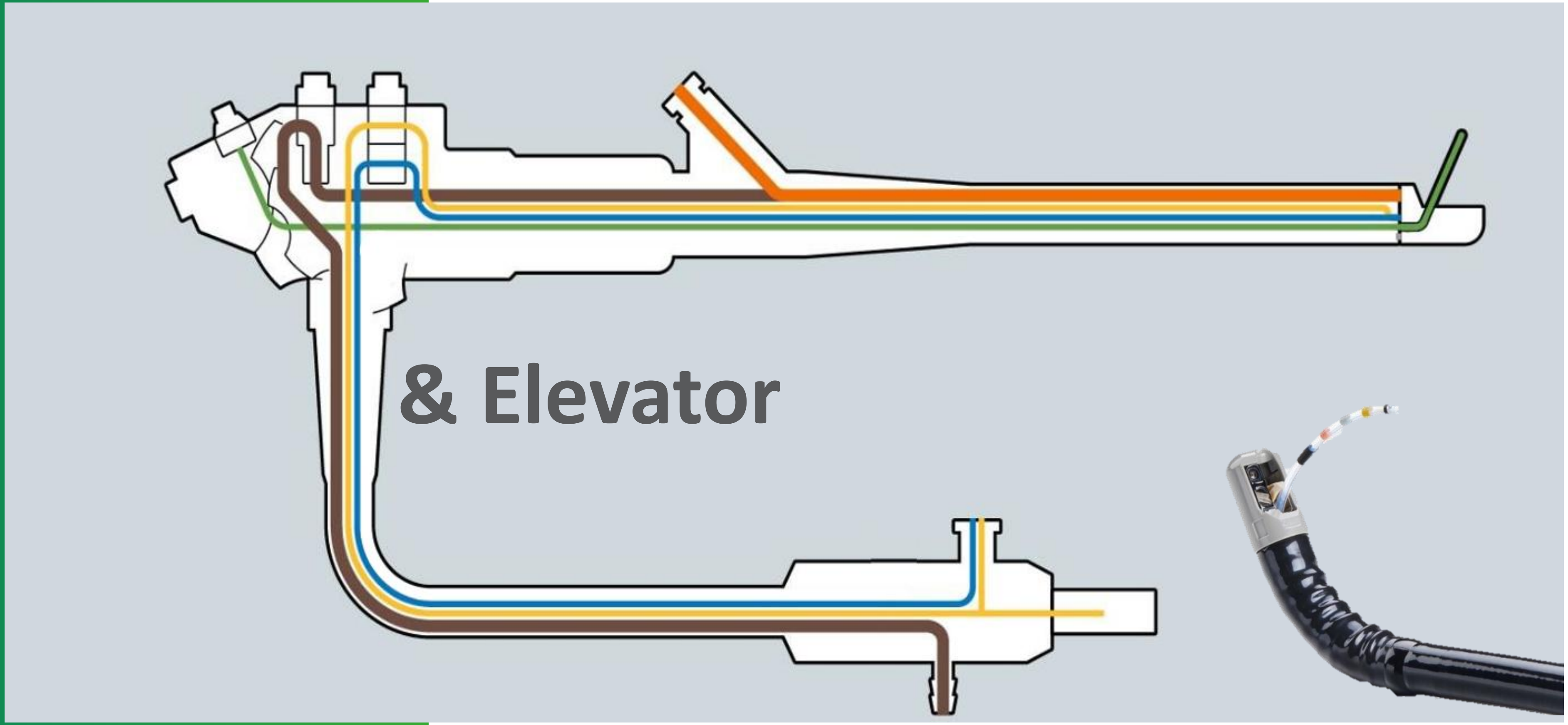
Gastroscope – Colonoscope - Duodenoscope

THE ENDOSCOPE CHANNELS



Colonoscope

THE ENDOSCOPE CHANNELS



Duodenoscope

ELEVATOR

Duodenoscopes & some ultrasound endoscopes

- Elevator wire
- Elevator channel open or sealed construction
- Complex construction of the tip
- Single use parts

Additional risk with duodenoscope

<u>the intended use</u>.

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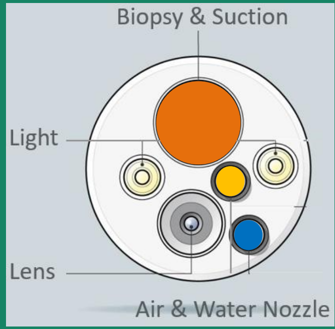
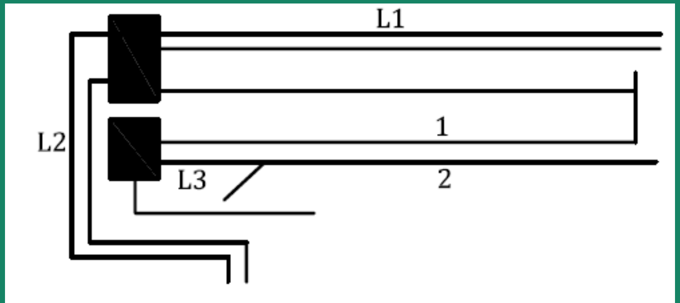
THE CHALLENGES FOR REPROCESSING

Interconnected channels

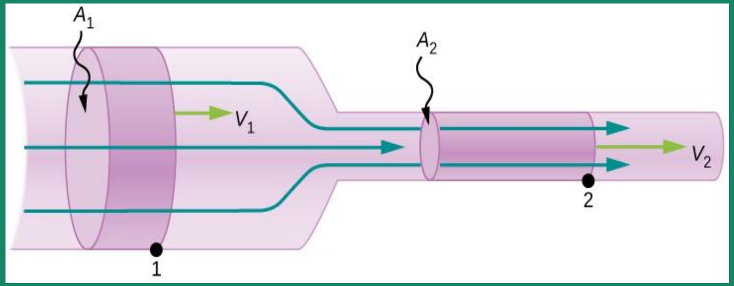
Different channels different diameters



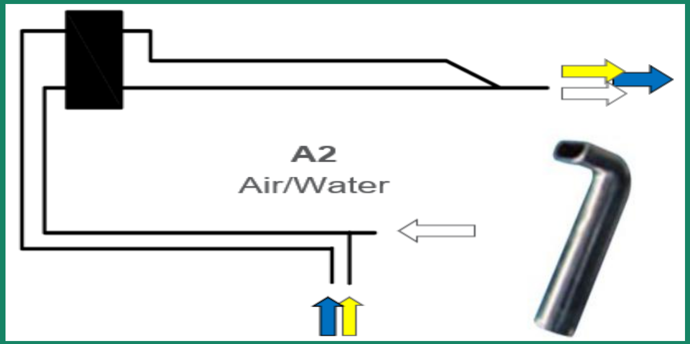
Complex constructions



Channel diameter variations



Multiple Inlets - One Nozzle Outlet



Many different endoscopes

- 1701 Endoscopes in WB-database
- 297 Different EWD connectors
- 209 Different DRY connectors
- No standard for connectors and ports.

THE ENDOSCOPE AND STANDARDS


Official Journal of the European Union

L 117

English edition

Legislation

Volume 60

5 May 2017

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I Legislative acts

REGULATIONS

★ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on


Nederlandse norm

NEN-ISO 8600-1

(en)

Optiek en optische instrumenten - Medische endoscopen en endotherapische toestellen - Deel 1: Algemene eisen (ISO 8600-1:2025,IDT)

Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements (ISO 8600-1:2025,IDT)

ISO 8600 sets a basic requirement that an endoscope must be cleanable. No, it does not provide detailed requirements or validation methods for cleanability (that domain lies with ISO 15883-4).

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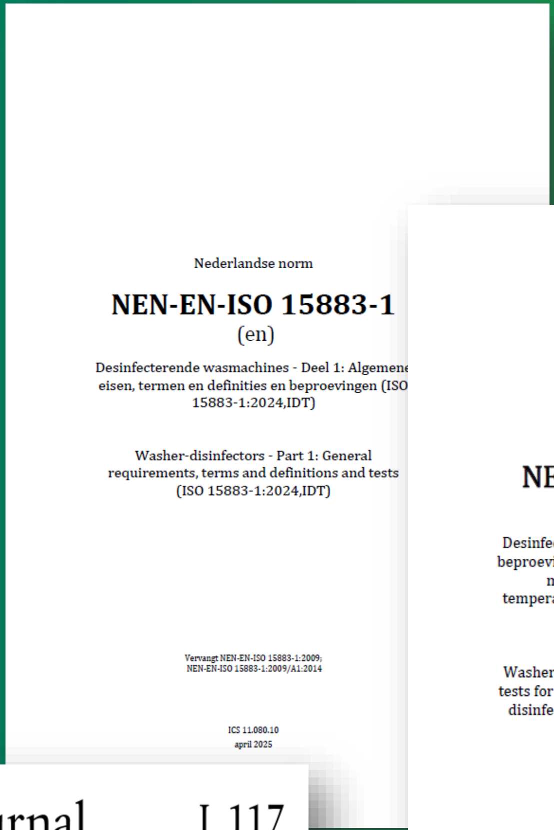
THE ENDOSCOPE WASHER, THE CHANNELS & COMPLIANCE



Nederlandse norm

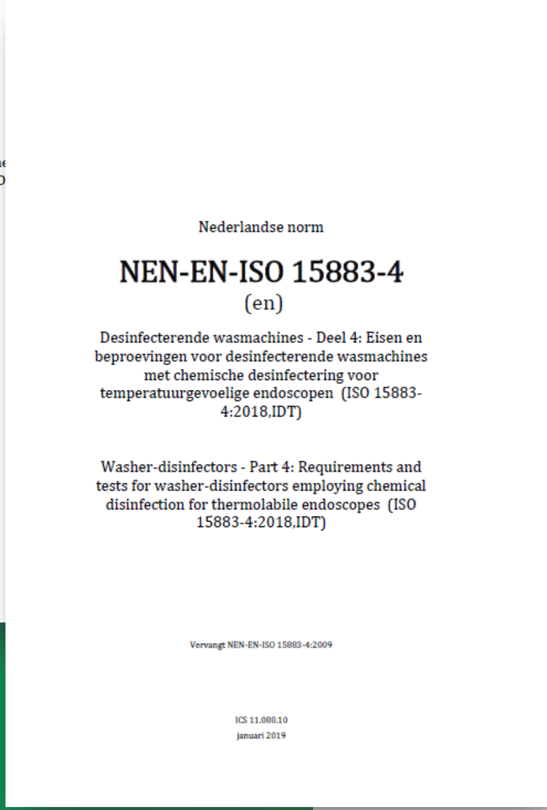
NEN-EN-ISO 15883-1
(en)

Desinfecterende wasmachines - Deel 1: Algemene eisen, termen en definities en beproevingen (ISO 15883-1:2024,IDT)

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2024,IDT)

Vervangt NEN-EN-ISO 15883-1:2009; NEN-EN-ISO 15883-1:2009/A1:2014

ICS 11.080.10
april 2025



Nederlandse norm

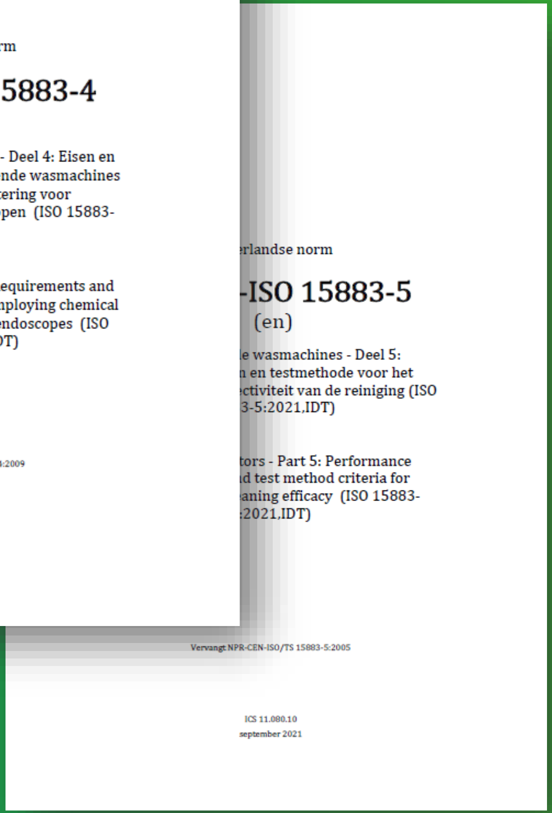
NEN-EN-ISO 15883-4
(en)

Desinfecterende wasmachines - Deel 4: Eisen en beproevingen voor desinfecterende wasmachines met chemische desinfectering voor temperatuurgevoelige endoscopen (ISO 15883-4:2018,IDT)

Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018,IDT)

Vervangt NEN-EN-ISO 15883-4:2009

ICS 11.080.10
januari 2019



rlandse norm

-ISO 15883-5
(en)

e wasmachines - Deel 5:
n en testmethode voor het
ctiviteit van de reiniging (ISO
3-5:2021,IDT)

tors - Part 5: Performance
d test method criteria for
aning efficacy (ISO 15883-
:2021,IDT)

Vervangt NPR-CEN-ISO/TS 15883-5:2005

ICS 11.080.10
september 2021

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REGULATIONS

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on

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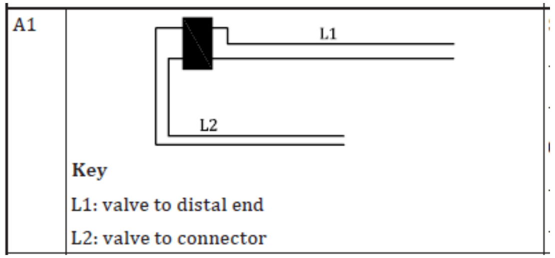
Table H.1 — Example for establishing relevant endoscope type test groups for WD type testing

Endoscope	Endoscope block	Channel connector	Separator (X)/ closure (Y)	Endoscope type test group (TTG)	Relevant for type test
1	A1	1	X1	TTG1	No - based on risk assessment
		2			
	B1	1	Y1		
		3			
2	A1	1	X2	TTG2	Yes - based on the risk assessment
		2			
	B1	1	Y1		
		3			
3	A2	1	X1	TTG3	No - based on risk assessment



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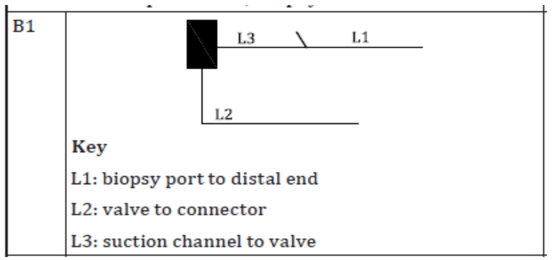

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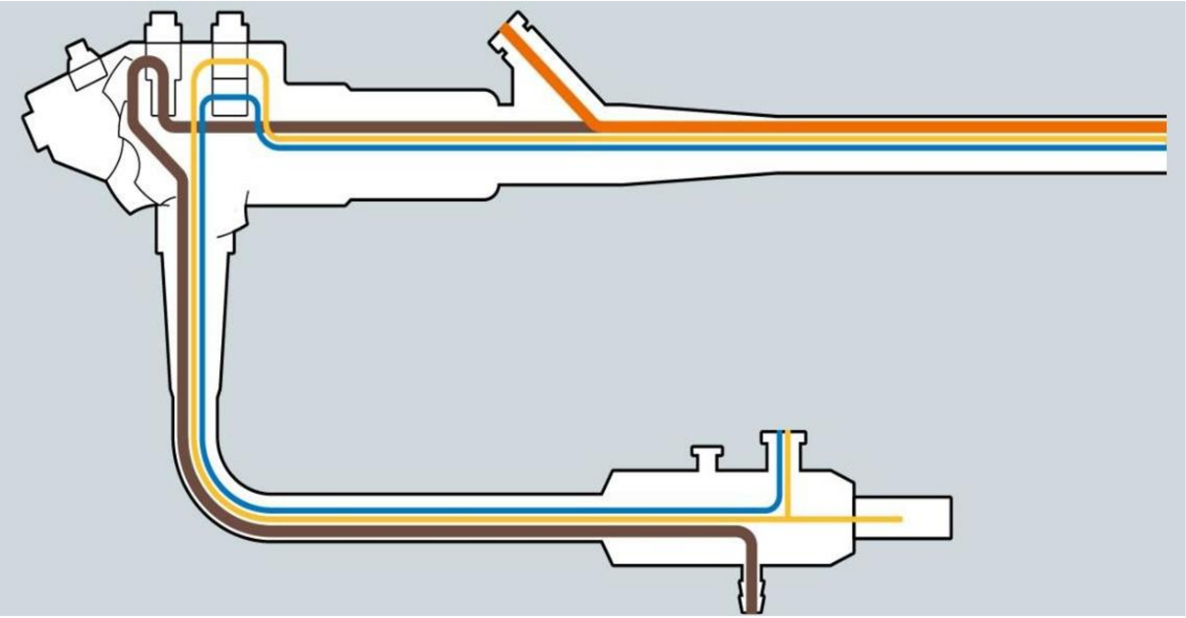
The base idea of the ANNEX H is to help us to define the relevant endoscopes for type testing.

If a new endoscope is similar to an excisting type test group the amount of testing can be reduced.

If a new endoscope does not belang to a previously established type test group then this endoscope must be fully tested and becomes the first member of a new type test group.



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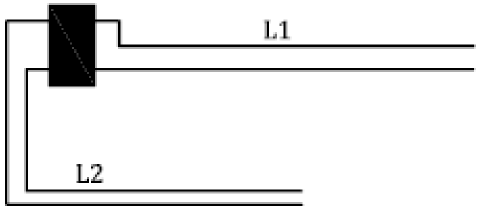
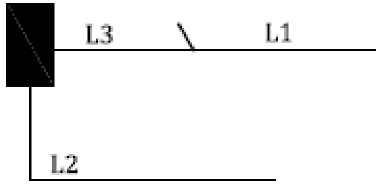
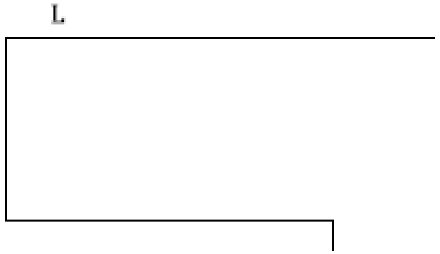
15883-4 ANNEX H EXPLAINED

- Block A: A1-A5: air and water channels
- Block B: B1-B7: Biopsy and Suction channels
- Block C: C1-C2: Waterjet / balloon channels

Annex H is embraced by the Endoscope manufacturers, most endoscopes are specified using the blocks and new blocks are provided.

Endoscope Block A, air/water channels		Specification
A1	 **Key** L1: valve to distal end L2: valve to connector	Single air channel and water channel: — not combined — Ø 0,7 mm ≤ d ≤ Ø 1,7 mm Channel lengths: — 600 mm < L1 < 2 600 mm — 800 mm < L2 < 2 000 mm

Endoscope Block B, Biopsy suction channels		Specification
B1	 **Key** L1: biopsy port to distal end L2: valve to connector L3: suction channel to valve	Biopsy/suction channel: — Ø 1,2 mm ≤ d ≤ Ø 2,5 mm Channel lengths: — 600 mm < L1 < 2 800 mm — 1 400 mm < L2 < 2 000 mm — L3 < 300 mm

Endoscope Block C, water jet channel/air balloon channel double balloon system		Specification
C1	 **Key** L: water jet or balloon connector to distal end	Water jet channel: — Ø 0,7 mm ≤ d ≤ Ø 1,6 mm — L = L1 of Block A — L = L1 of Block A + L2 of Block A

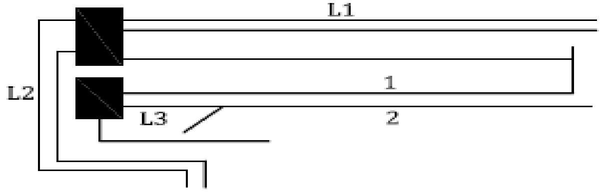
15883-4 ANNEX H EXPLAINED

- Block D: Elevator channels
- Block E: E1-E2: small diameter endoscopes
- Additional Endoscopes that cannot be divided into Blocks (4 diagrams)

Annex H is embraced by the Endoscope manufacturers, most endoscopes are specified using the blocks and new blocks are provided.

Endoscope Block D, elevator channel		Specification
D	 **Key** L: control body to distal end	Elevator channel: — Wire: Ø 0,3 mm ≤ d ≤ Ø 0,8 mm — Channel: Ø 0,8 mm ≤ d ≤ Ø 1,2 mm — Delta 0,1 mm ≤ d ≤ 0,4 mm Channel lengths: — 1 000 mm < L < 1 700 mm

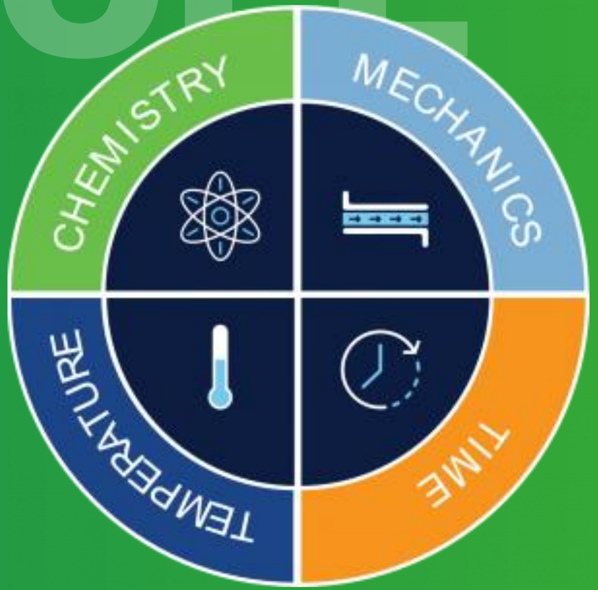
Endoscope Block E, small diameter endoscopes (e.g. cystoscopes, bronchoscopes)		Specification
E1	 **Key** L: biopsy port to distal end	Biopsy/suction channel: — Ø 0,5 mm ≤ d ≤ Ø 3,4 mm Channel lengths: — 300 mm < L < 1 000 mm

Diagrams of endoscopes that cannot be divided into endoscope blocks due to interconnections between water/air and biopsy/suction channels or combinations with balloon channels	Specification
 **Key** 1: balloon channel 2: biopsy/suction channel L1: air/water channel to distal end L2: valve to connector L3: suction channel to valve	Ultrasound endoscope Air channel and water channel: — Ø 0,8 mm ≤ d ≤ Ø 1,2 mm Biopsy/suction channel: — Ø 1,2 mm ≤ d ≤ Ø 2,5 mm Balloon channel: — Ø 0,8 mm ≤ d ≤ Ø 1,2 mm Channel lengths: — 1 200 mm < L1 < 2 200 mm — 1 400 mm < L2 < 2 000 mm — L3 < 200 mm

Essential:

to create contact between the proces fluids and all surfaces of the endoscope.

THE ENDOSCOPE WASHER



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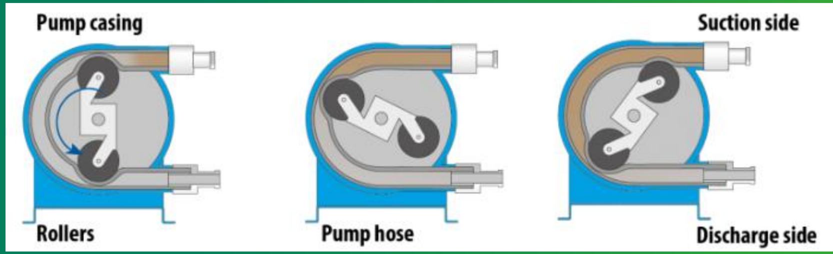
To create a process situation in which all channels and cavities are reached by the process fluids.

Process monitoring: Verification that the above actually takes place.

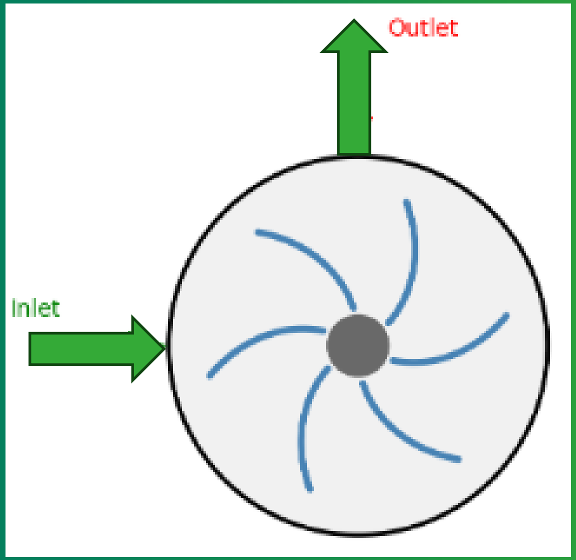
Process traceability: Recording process data as evidence of a proper process.

THE DIFFERENT CHANNEL PUMP SYSTEMS

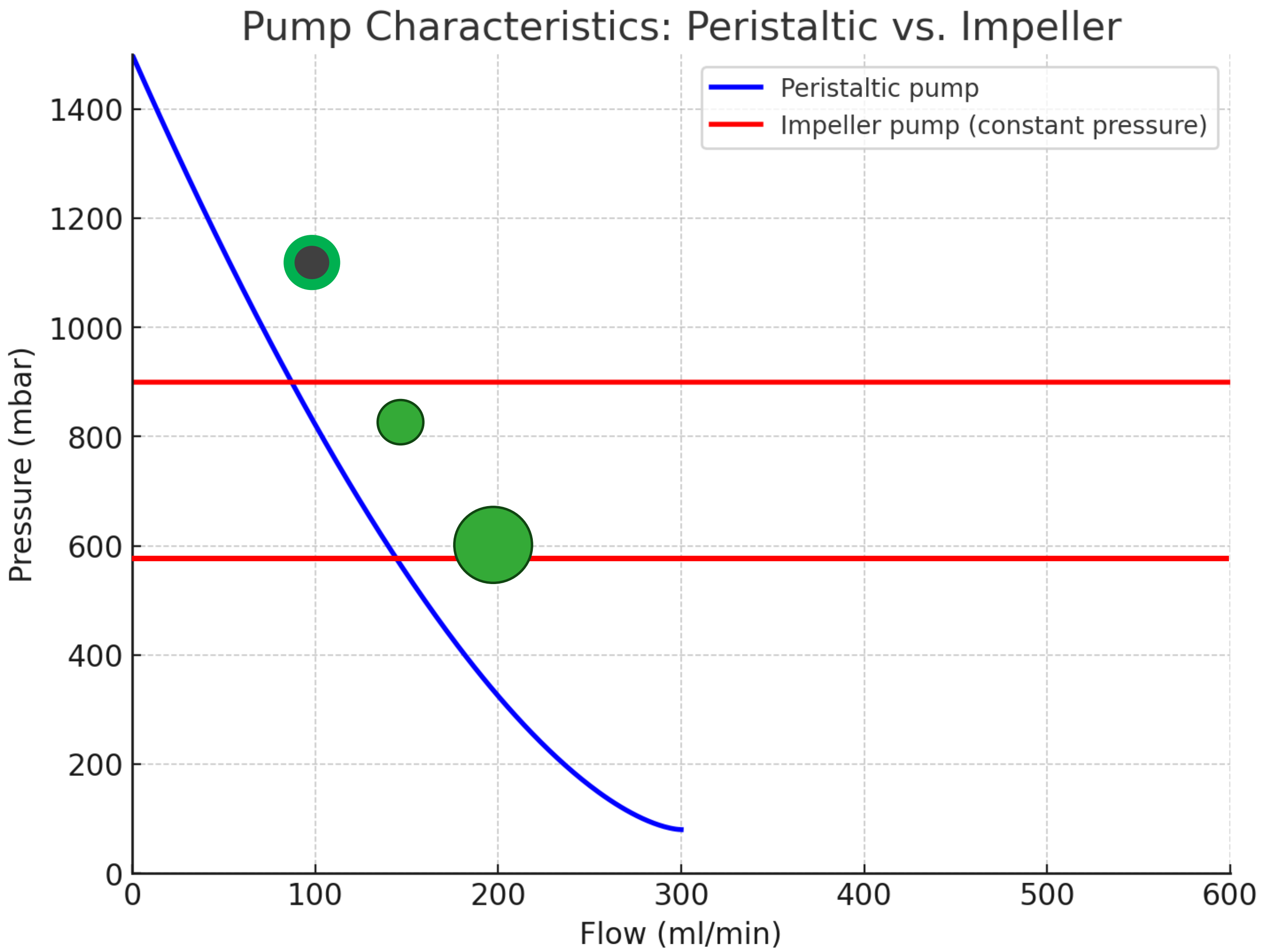
Peristaltic pumps



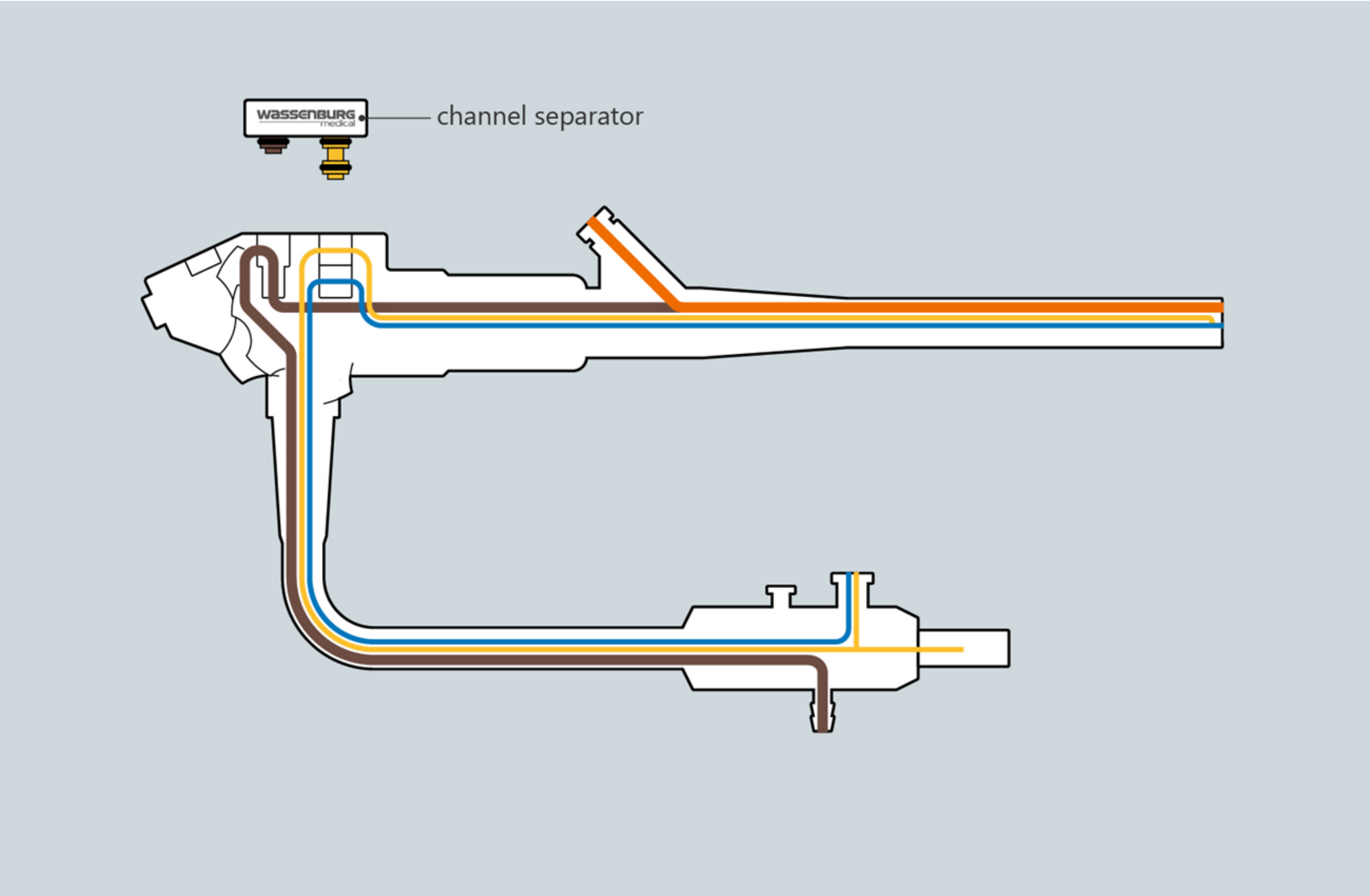
Centrifugal (Impeller) pumps



Combination of both



CHANNEL SEPARATION



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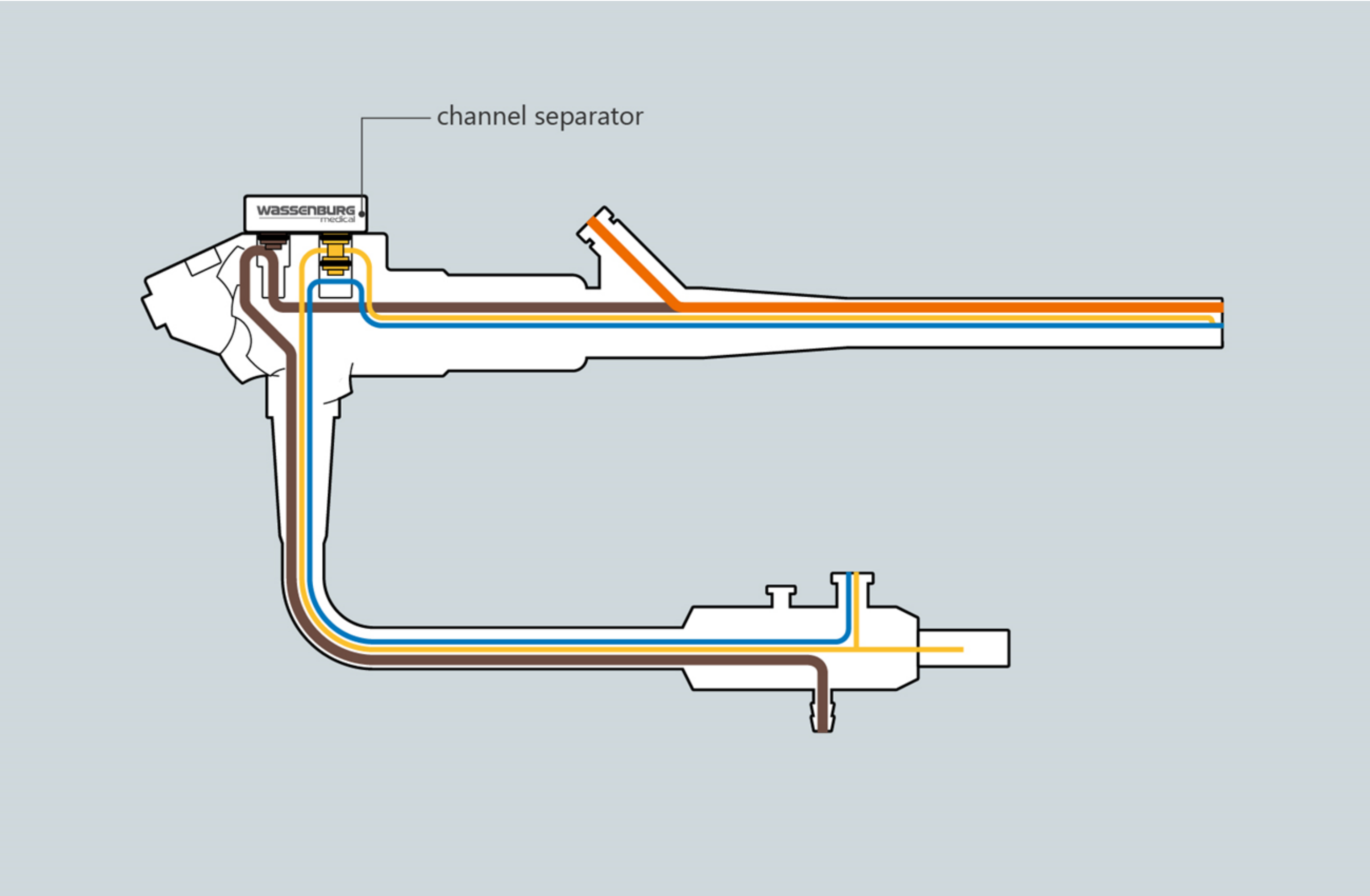
CHANNEL SEPARATION



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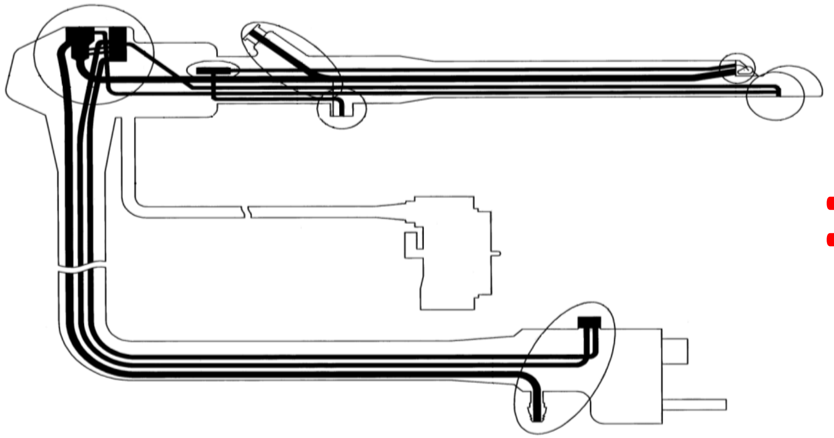
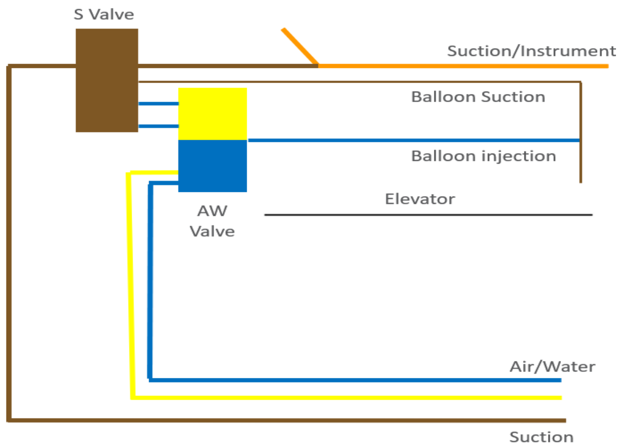
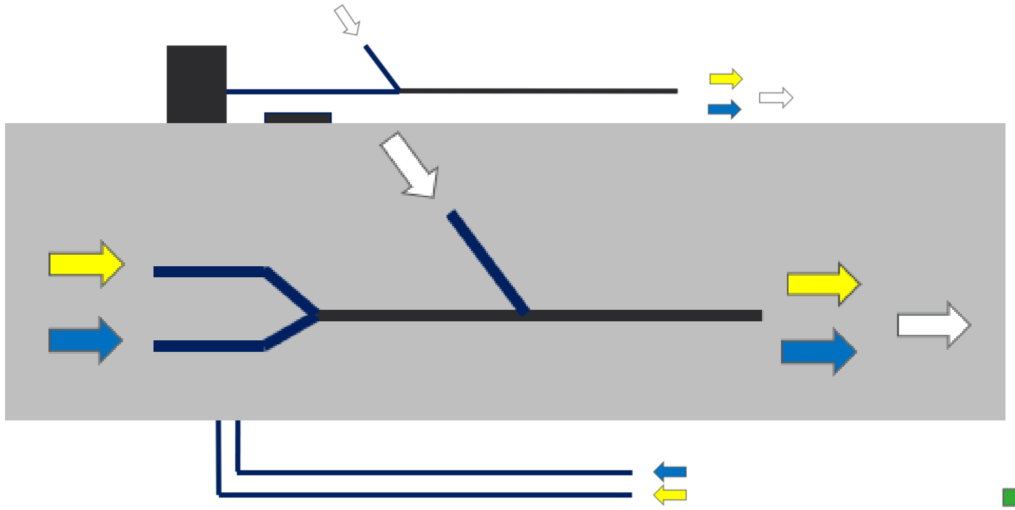
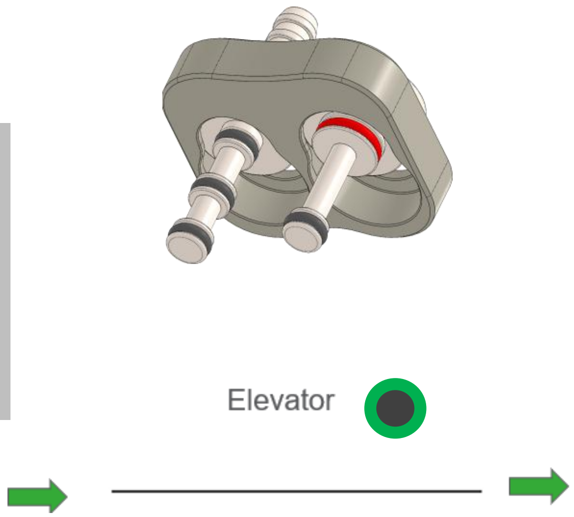


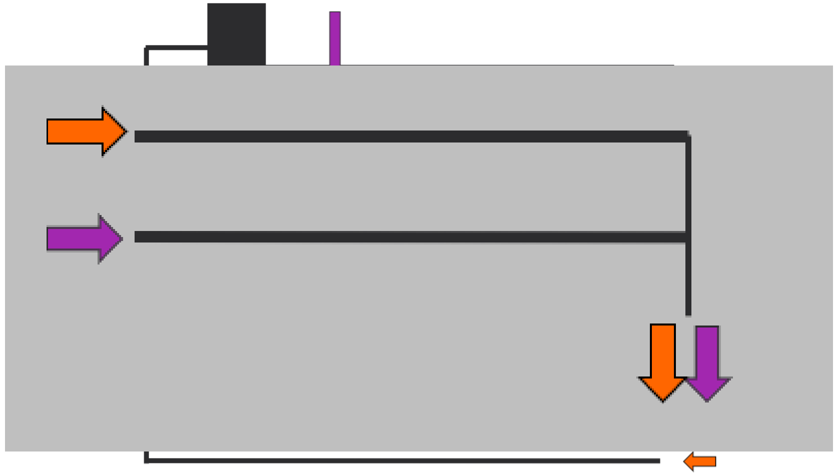


- Air channel
- Water channel
- Biopsy channel
- Suction channel
- Balloon injection channel
- Balloon drain channel
- Elevator channel

KEY IS TO ISOLATE THE CHANNELS, DIRECT THE FLOW AND MAKE MONITORING POSSIBLE



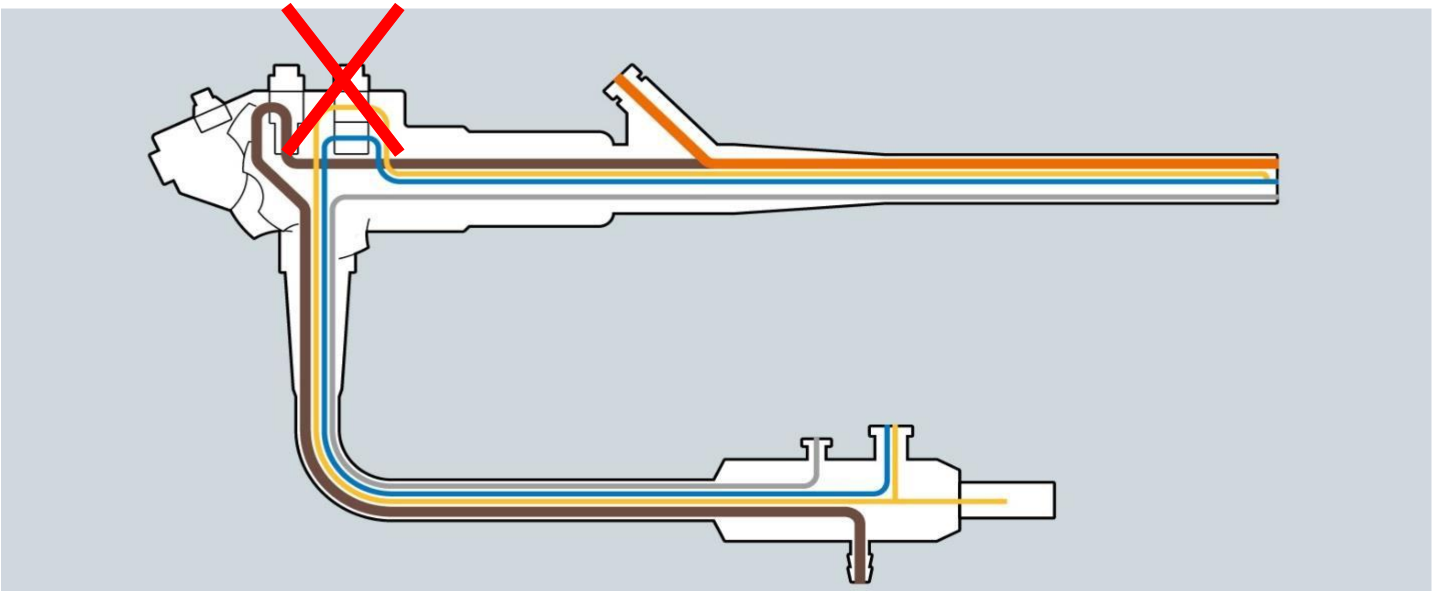




INNOVATION ON ENDOSCOPES AND MY DREAM ENDOSCOPE

Single use parts for complex constructions

Simplifying constructions



THANK YOU !

QUESTIONS ?

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For every patient a safe endoscope