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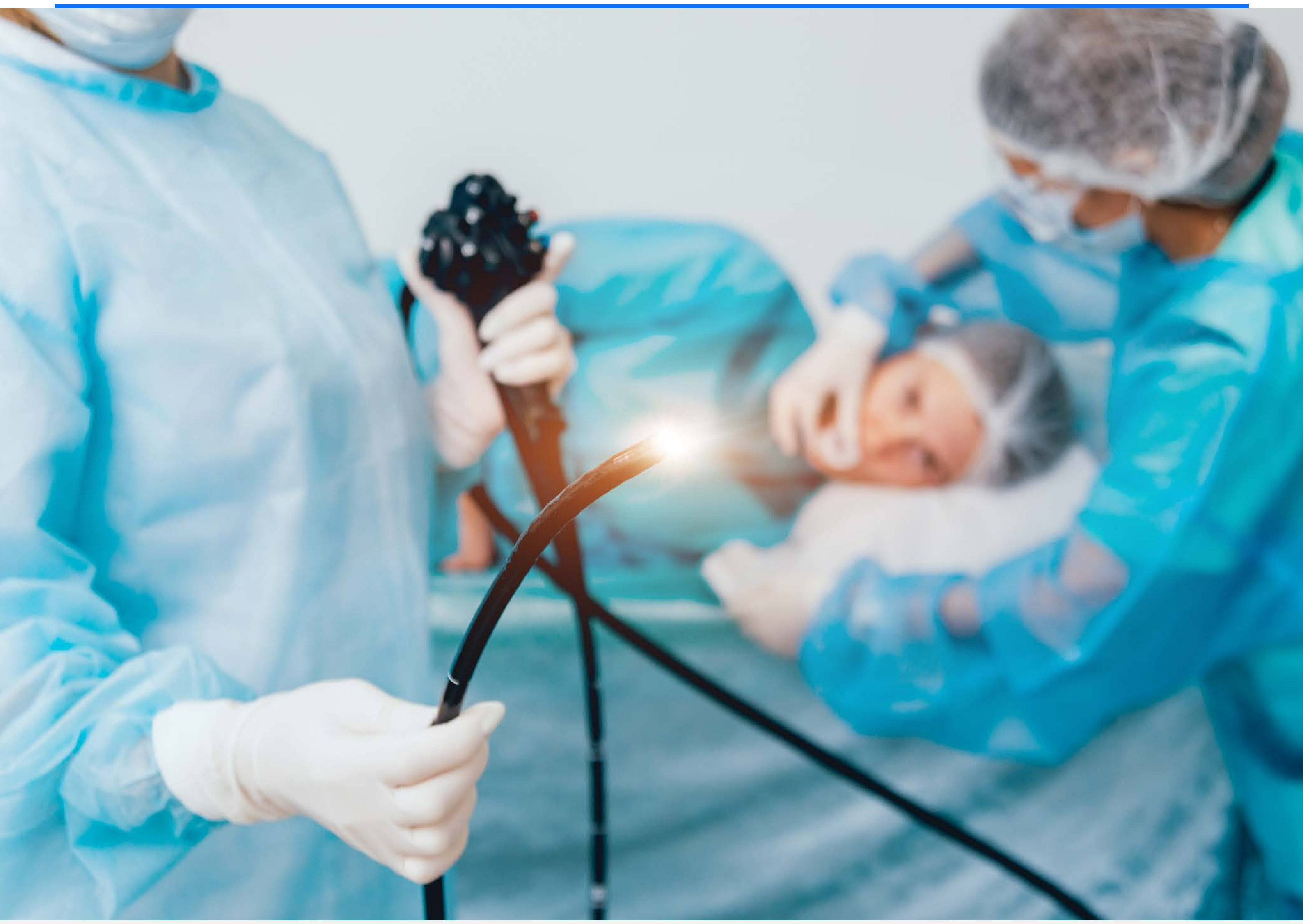


# Designing single-use endoscopes: Smaller, cleaner, cheap enough?

*By Dall Amos, Euan Morrison and Rob Morgan*

Endoscopes are essential visualisation tools in modern medicine. Due to cleanliness concerns with flexible devices, single-use endoscopes are beginning to play an increasing role in this space. However, several hurdles to further market penetration remain, such as product cost and wastage. Furthermore, there is an increasing push in endoscope design towards miniaturisation as a means to improve usability and reduce patient trauma, which requires the consideration of cost/size/performance trade-offs.

In order to explore the technological and logistical challenges associated with designing systems that address both these aspects, the medical team at Sagentia conducted an internal project to develop a miniaturised sub-1.5mm scope tip using off-the-shelf hardware. This was done by considering possible illumination and imaging options based on size constraints, as well as designing the assembly and mounting while considering availability and costs. While the process does not have significant technical complexity it is limited by the technological performance of existing hardware and the challenge lies in assembling at such small scales. To that end, the modularity of parts being distributed by the likes of **OmniVision** and **Schott AG** is of benefit. One player in the space of single-use endoscopes is **Ambu A/S**, which plans to release single-use colonoscopes and gastroscopes in 2021.

## Endoscopes in focus

Endoscopes are an essential tool in many modern surgical procedures. Equipped with one or more cameras and light sources, they allow doctors to examine multiple internal cavities in the human body.

### Types of endoscopes:

- Ureteroscopes; for urinary tract use
- Colonoscopes; for large intestine use
- Laparoscopes; for abdominal use

They may function alongside surgical tools in so-called keyhole surgery, a minimally invasive procedure in which scopes and tools are passed into the patient's body via small external incisions.

Existing endoscopes are mostly sophisticated, multi-use devices that may come with various technological enhancments such as customisable lighting units, fine distal tip articulation using angulation wires, and multiple camera chips to allow stereoscopic vision.

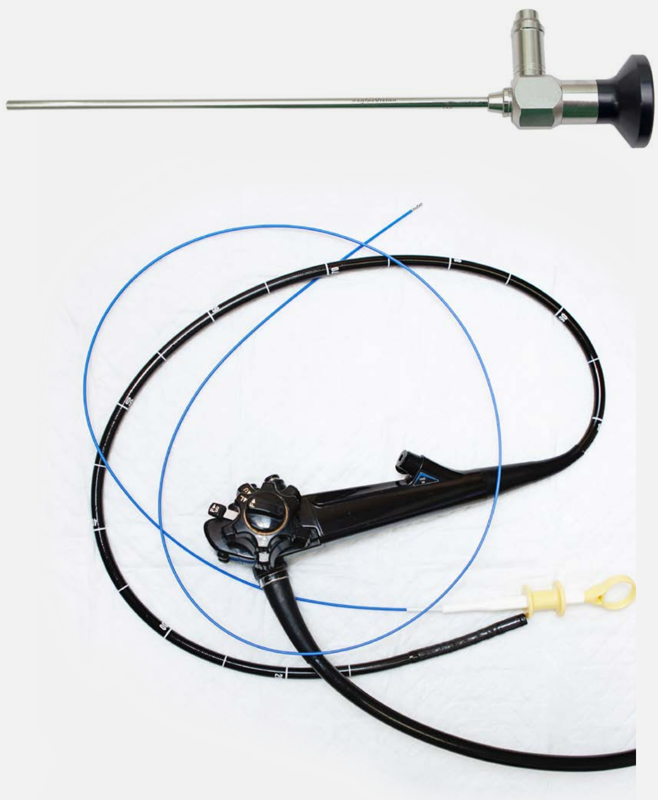


*Figure 1: Endoscopes generally fall into two categories: rigid, as with the Olympus sinuscope (top) and flexible, as with the Olympus duodenoscope (bottom). Flexibility enables mobility where it is needed, and thus the two types are typically segregated based on the intended area of use in the body. Images sourced from [1], [2].*

However, some reusable endoscopes may suffer from issues with cleanliness between surgical procedures. According to the American Journal of Infection Control [3], as many as 71% of reprocessed endoscopes can contain some form of microbial growth, leading to potentially severe complications that can ultimately compromise patient health. The problem mostly affects procedures involving flexible endoscopes (see Figure 1) [4], which generally do not undergo the high temperatures of a steam sterilisation process, instead being suitable for only high-level disinfection [5]. In particular, in 2013 the Centers for Disease Control and Prevention (CDC) found a potential association between multi-drug resistant bacteria and improper cleaning of flexible duodenoscopes [6]. The FDA has issued warning letters to several endoscope manufacturers as a result [7].

Single-use flexible endoscopes have emerged as a possible solution to this issue. Being disposable, they offer the cleanest path to preventing infection between patients. In recent years, they have begun to reach comparable cost-effectiveness to their reusable, flexible counterparts (see Figure 2) [8] - in fact, low-volume healthcare centres can achieve significant savings by making the switch to such devices in appropriate procedures [9].

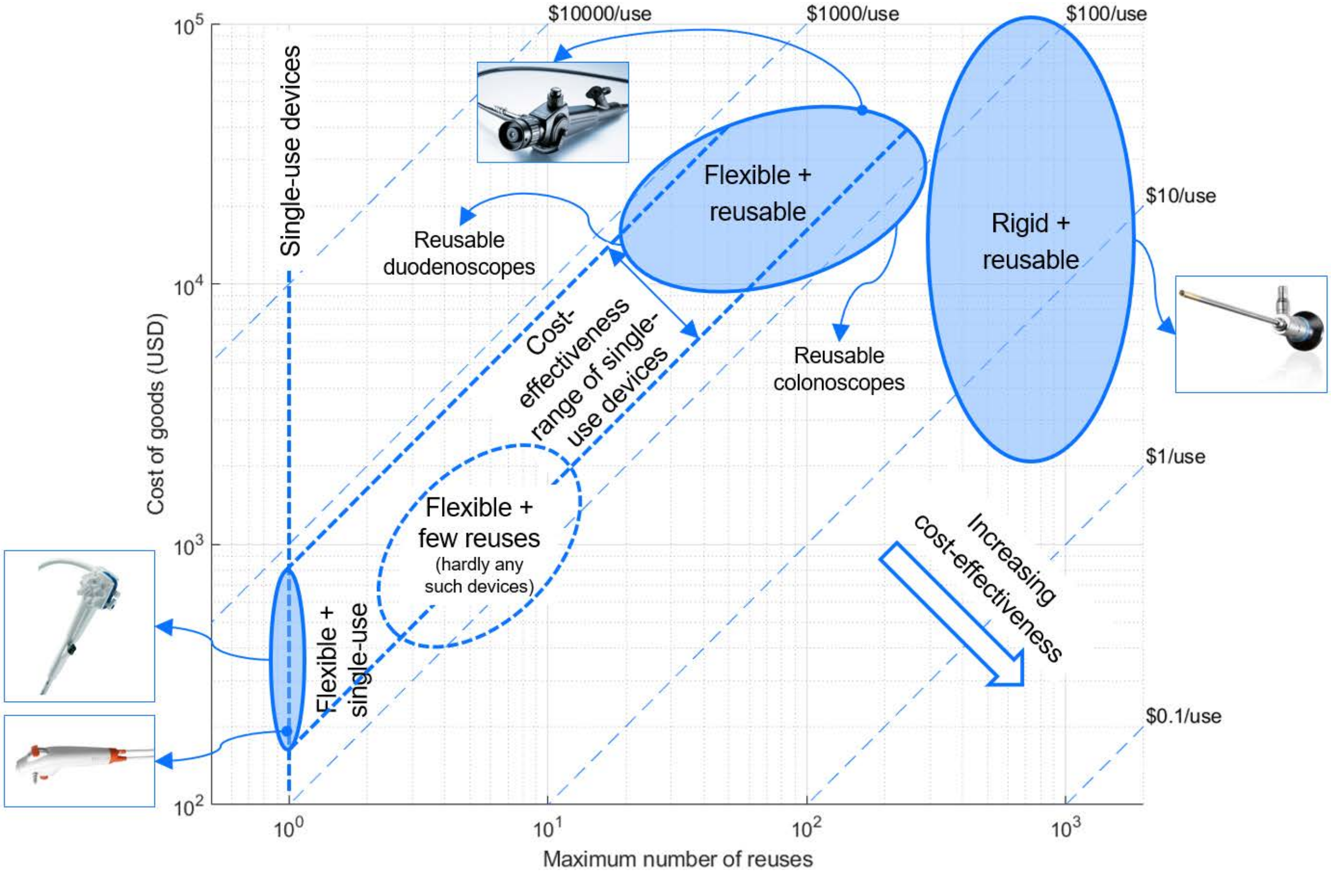



*Figure 2: Cost vs maximum number of reuses for various categories of endoscope, with cost-effectiveness shown as contours of cost per use. Flexible, single-use endoscopes can reach comparable or better levels of cost-effectiveness compared to their reusable counterparts when the added costs of reinfection from reusable devices are considered [10]-[12]. Rigid endoscopes do not suffer from the same cleanliness issues as flexible ones, so single-use rigid endoscopes are not necessary.*

## The endoscope market

The market for endoscopy is sizeable; the global value was estimated at USD 35.14 billion in 2018 (of which endoscopes themselves comprise about USD 1.4 billion) and it is expected to grow at a rate of 7.4% annually [13]. Yet despite the push by regulatory bodies towards single-use scopes to mitigate the contamination risks of reusables, there are still several major hurdles to increased market penetration.

### Cost per procedure

The reuse of traditional flexible endoscopes renders them more cost-effective for higher-volume centres such as hospitals [9], for whom the total cost per procedure can be under US$200. There is therefore a need to reduce the cost of single-use devices, while still addressing trade-offs with performance such as image quality.

### Sustainability

In addition, disposable scopes can be perceived as less ecologically friendly. In an era where manufacturers increasingly need to consider long-term sustainability in medical device design, striking an effective balance is not always straightforward. It requires making a judgement call, based on a consideration of multiple complex factors[8].

### Device miniaturisation

There is an increasing push in multiple areas of medicine towards device miniaturisation [14], [15]. A key market driver towards endoscope miniaturisation is improved ease of use during procedures through increased scope manoeuvrability and by enhanced access to previously inaccessible areas of the body. Furthermore, smaller scopes can reduce patient trauma following interventional procedures and surgery.

The limitations are clear: single-use flexible endoscopes have potential but need to be made smaller and cheaper to increase market penetration. In order to ascertain the technical challenges associated with product development in this space, Sagentia conducted an internal project to investigate the capabilities of a simple chip-on-tip endoscope, discussed herein.

## Manufacturing a flexible, single-use endoscope

The brief here was simple: to construct an illumination and imaging device with a tip diameter of <1.5mm using low-cost, off-the-shelf hardware. While endoscopes generally also feature angulation wires for tip control, this was not considered here.

## Disposable endoscope design

### Illumination

Endoscope illumination generally falls into two categories: fibre-coupled or LED-on-tip (see Figure 3).

LED-on-tip methods are the most straightforward. LEDs may be positioned near or on the distal tip to light the target. This often results in a trade-off between illumination intensity, uniformity, efficiency and size. Heating effects may also need to be considered for very bright light sources.

The approach more often used by larger endoscopes is fibre-coupling. The designer has considerably more freedom to choose the light source here due to its positioning further upstream. Optimising for intensity and colour performance without too much concern for size and cooling requirements allows for very effective illumination. This is then directed to the tip via an optical fibre bundle, whose individual cores can be positioned to ensure sufficient uniformity. However, these approaches add increased manufacturing complexity, and may limit the mobility of the distal tip due to the minimum bend radius of the fibre core.

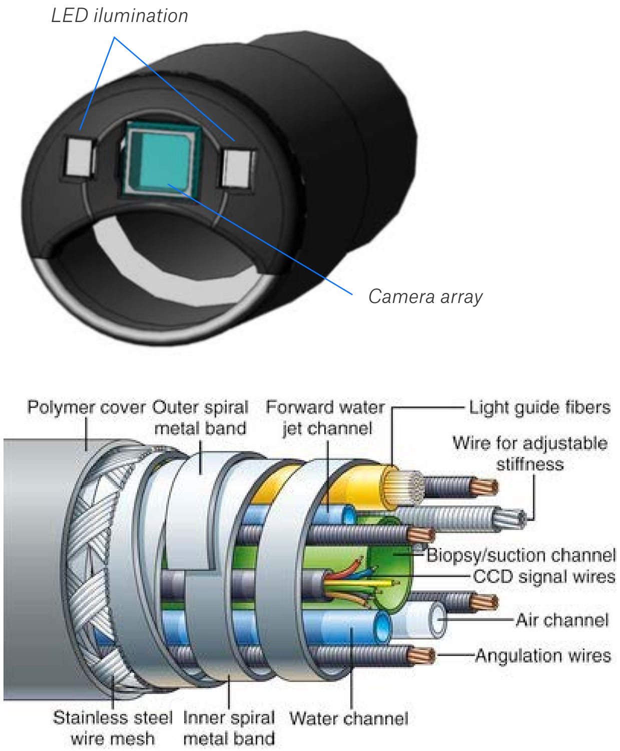
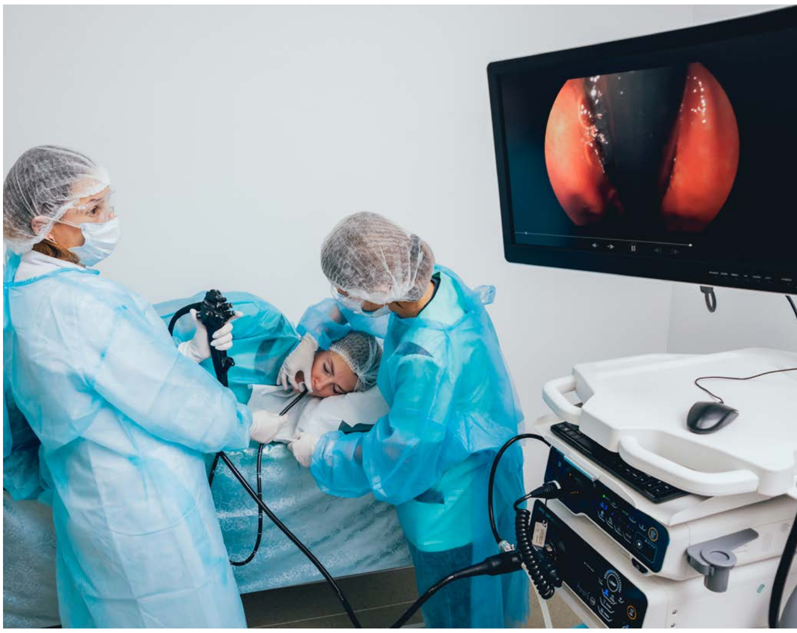



*Figure 3: The LED and camera chip-on-tip approach (top) mounts the camera and illumination components directly to a PCB at the scope tip. This can save space in the scope channel (bottom) by eliminating the need for light guide fibres. Images sources: [1], [16].*

## Imaging options

A wide range of imaging options exists, depending on the price point of the endoscope. Almost all models feature CMOS camera arrays, though these can vary greatly in resolution (and consequently array size) right up to 8K [17]. Sophisticated, reusable devices may contain multiple cameras, such that their relative separation can enable stereoscopic vision. Fluorescence techniques may also be used to aid surgery, though these tend to be more common with rigid rod endoscopes rather than the flexible, chip-on-tip kind.

The distal tip size-performance trade-off is very much limited by pixel size, which is reaching a stage of diminishing returns (see Figure 4). This means that camera resolution (i.e. number of pixels in a camera array) is dependent almost entirely on package size. Advances in self-contained miniaturised imaging packages by developers such as OmniVision [18] have made it easily possible to source very small imaging arrays with a form factor of under 1mm$^2$, complete with integrated wafer-level optics. While not offering HD resolution, these are often adequate for many endoscopy applications.



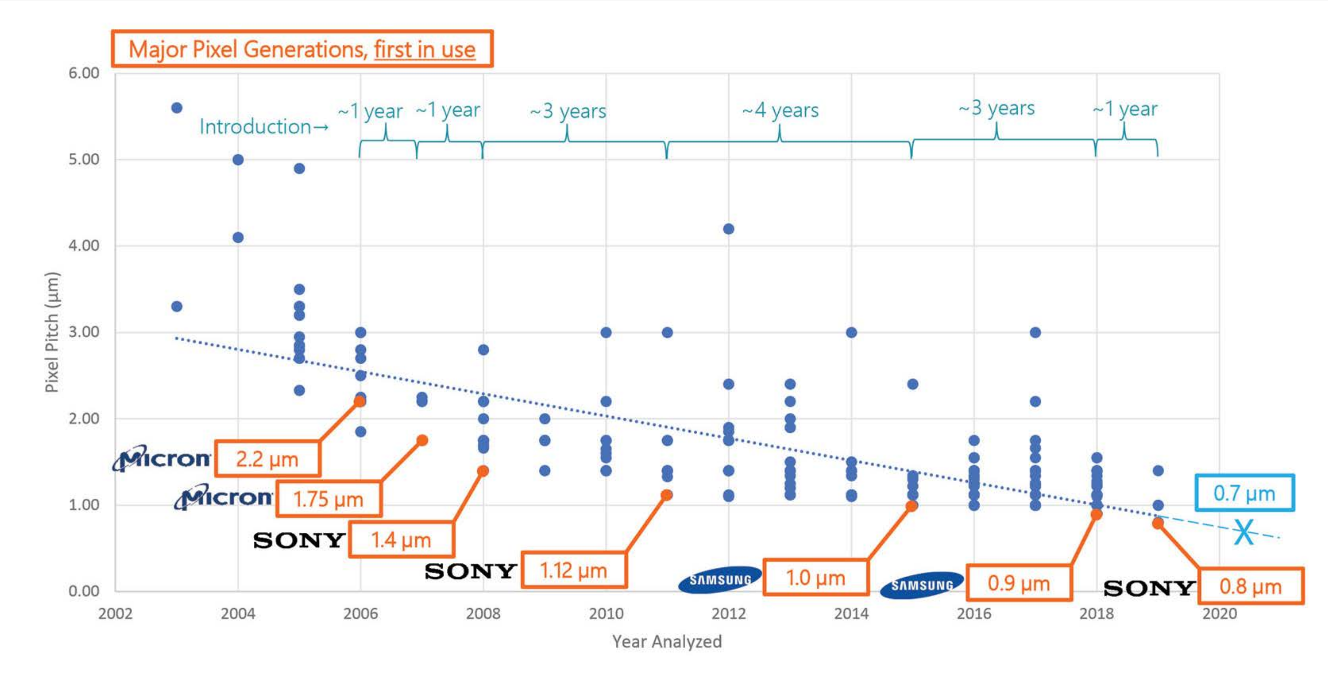



*Figure 4: Pixel pitch (a proxy for camera size/resolution) for mobile sensors as a function of time. The rate of pixel pitch reduction is decelerating, suggesting a point of diminishing returns for the size-resolution trade-off (though other aspects of performance are still seeing development). Graph adapted from [19], [20].*

### Selection

For small, low-cost applications, the key parameters driving endoscope design are manufacturing simplicity and the ability to tightly integrate the electronics at the distal tip. Sagentia therefore opted for a miniaturised OmniVision camera and white LEDs to construct the single-PCB chip-on-tip assembly. The essential systems for camera operation could be put together very quickly, and design of a mechanical assembly to hold the components would be straightforward. A simple 2-LED configuration was sufficient to achieve reasonable uniformity at the required working distance.

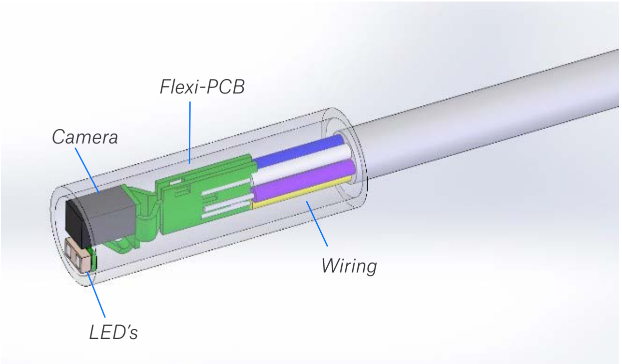



*Figure 5: Rendered CAD (top) and internal arrangement (bottom) of the miniaturised scope tip. While optimally the 2 LEDs would be placed either side of the camera, we opted to move them below it to reduce the cross-sectional area*

## Challenges and solutions

Most design challenges faced here relate to the optimisation of colour performance, illumination intensity, uniformity of illumination and effective imaging under the size constraints.

- Colour performance is entirely dependent on the LED selection – within the small tip, it is undesirable to add additional components such as filters to modify this.
- Light intensity is a function of component selection and driving current. Very high driving currents can lead to significant tip heating which is undesirable even for single-use devices. Camera parameters can also be adjusted to optimise image quality to an extent.
- Uniformity and effective imaging are achieved by optimising the relative component positions at the tip.
- Further issues such as matching the field of illumination to the camera field of view to maximise efficiency are a function of LED selection and the imaging optics.
- Latency can also pose a problem during live surgery, as any time lag is detrimental to efficacy. Endoscopes used in surgical applications may have fewer options in terms of communication and processing components. For instance, they may be limited to wired communication and field-programmable gate arrays which offer faster performance.

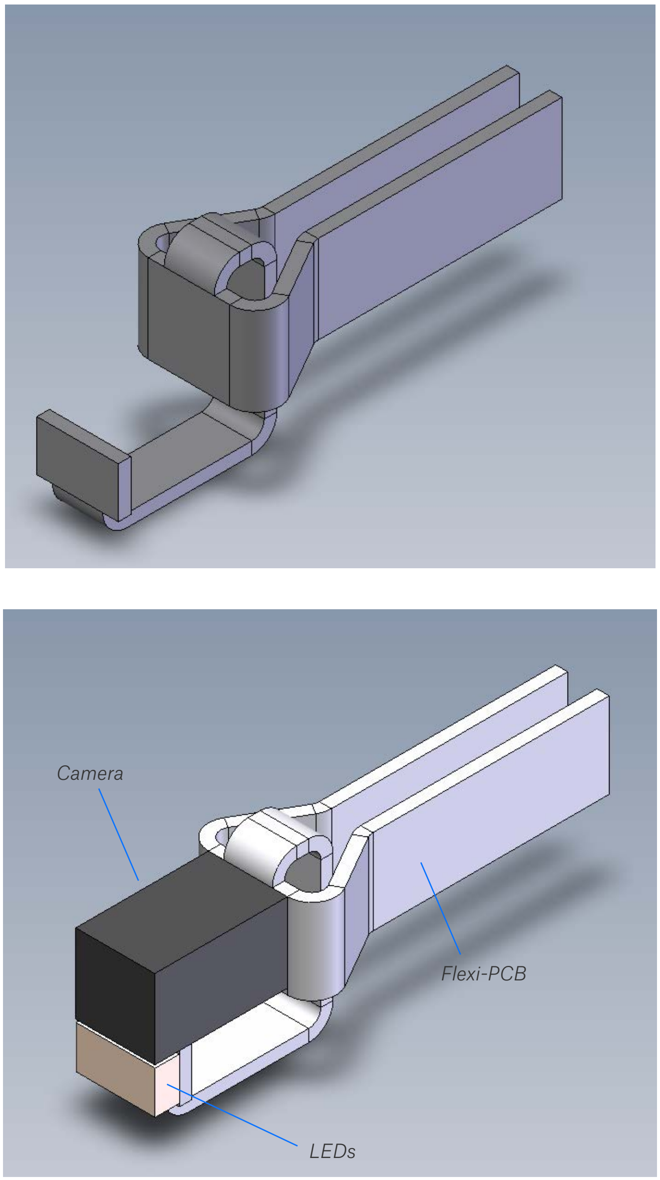



*Figure 6: Flexi-PCB (top) and flexi-PCB with camera and LEDs (bottom), as located in the scope tip.*

It is unusual to find LED and camera components that match each other in height. This means that PCB mounting may either lead to shadowing of the illumination by the camera or blocking part of the image by the light source. Possible workarounds once again introduce a cost-performance trade-off; most manufacturers opt to raise the camera head above the LEDs, with the result that the centre of the image may be slightly dimmer than the extremities. A costlier but more elegant solution is to mount the two assemblies on separate stiff PCBs, or a single flexi-PCB setup, as we did (see Figure 6).

Effective sealing of these fine electronic components against body tissue and fluids is crucial for effective utility of these endoscopes. A low-cost solution to this lies in the field of resins; many modern single-use devices utilise material such as clear epoxy to protect the lighting and camera systems while still ensuring adequate illumination and imaging.

Furthermore, a side-effect of miniaturised electronics is their increased susceptibility to electrical interference from nearby devices; endoscopes are often inserted into the body alongside electromechanical and electrosurgical operating tools. Chip-on-tip assemblies therefore need to take EMC – from both a reception and emission perspective – into account.

## The future for single-use flexible endoscopy

As is evident, the issues faced here are not technically complicated – rather, they simply run into the fundamental technological limitations of size against performance. Machining at such small scales is challenging which is a problem facing the entire surgical industry.

There is a great deal of room for further development in this space, both technical and logistical. Increased flexibility of the distal tip is a major advantage from a manoeuvrability perspective. The ability to optimise manufacturing workflows so as to maintain a low unit cost is another big plus – to that end, endoscope part producers such as Schott AG have begun to ease assembly with increased modularity [24].

One player in this space of flexible endoscopy is Ambu A/S, whose single-use duodenoscope (see Figure 7) [22] recently gained FDA approval. Ambu plans to release both a single-use colonoscope and gastroscope in 2021 [23], which may increase the market penetration of disposables into traditionally reusable-scope environments.

Integrated feature recognition is another area where we expect to see further advancement, through technologies such as multispectral remote sensing. This capability offers major benefits during surgical applications, although at present integrating it with single-use scopes is a challenge.

Overall, the future for single-use flexible endoscopy market looks bright; estimated at USD1 billion in 2019, it is expected to grow at a compound annual rate of 19.8% [25]. Further development for commercial devices should focus on reducing costs. Technologically, most innovation is likely to occur via the implementation of smarter computer vision software techniques to maximise the capabilities of miniaturised camera systems (as these are independent of the size constraints). Hardware improvements in this space are likely further off.

There is potentially also a gap (shown by the dashed region in Figure 2) for flexible devices with a small number of reuse cycles, into which single-use devices could expand. These might provide a best-of-both-worlds solution, balancing sustainability and cross-contamination concerns to an acceptable level, so long as such scopes are suitably designed for effective cleaning and sterilisation between uses.

In the long term, we expect a migration of the single-use endoscopy market towards ultraminiature solutions of smaller size than our proof-of-concept, such as the various micro-endoscopes being tested in academic spheres [26]–[29], as well as the growth of wireless 'capsule' endoscopy (largely for GI applications) due to continuing advances in active locomotion of the capsule (see Figure 8) and image analysis using artificial intelligence techniques [30].


*Figure 7: The Ambu® aScope™ Duodeno duodenoscope (top) and Ambu® aScope™ Broncho bronchoscope (bottom), both single-use flexible devices. [23], [24].*

*Figure 8: The NaviCam™ capsule micro-endoscope. This single-use miniature solution enables the digestive tract to be visualised in real-time, with magnetic fields being used to control the capsule to 5mm precision [31].*

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For further information visit us at:

www.sagentia.com
or email info@sagentia.com
www.sciencegroup.com

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**Sagentia Ltd**
Harston Mill
Harston
Cambridge
CB22 7GG
UK

**Sagentia Ltd**
First Floor
17 Waterloo Place
London
SWY 4AR
UK

**Sagentia Inc**
44 School Street
Suite 505
Boston
MA 02108-4209
USA