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Prospects of CRC endoscopic screening

Part 1
Aseptic method of infection safety of colono- and gastroscopy

"The risk associated with improperly cleaned, disinfected, and sterilized endoscopes is the "most critical patient safety issue I have encountered in my 30 years in healthcare" Nancy Chobin, 2011, [1]:

Contents of slides

1. Risk of cross-infection (CI) of patients with colon- and gastroscopes.
2. Business and risk of CI.
3. Multi-channel endoscope.
4. What creates the risk of CI.
5. Base of Aseptic method of infection safety of colono- and gastroscopy.
6. 1-channel endoscope.
7. Illustrations to the method of HLD, storage and transportation of 1-channel endoscope.
8. Comment to the method of HLD, storage and transportation of 1-channel endoscope.
9. Differences of the new method of infection safety of colono- and gastroscopy.
10. Conclusion.
11, 12. Basic sources of information.
13. *Enclosure 1:* 2013 year's data about CI risk from Lawrence F. Muscarella PhD [15].
14. *Enclosure 2:* 2014 year's data about CI risk from Lawrence F. Muscarella PhD [15].
15. *Enclosure 3:* Key details, bundles and aspects of the Aseptic method.

1. Risk of cross-infection (CI) of patients with colon- and gastroscopes

The ECRI (USA) forecasts annually top 10 most hazard procedures: in 2010 CI risk was on the 1st place, in following years - on the 3rd, 4th, 8th. In 2014 CI risk will increase again – tooks the 6th place [2].

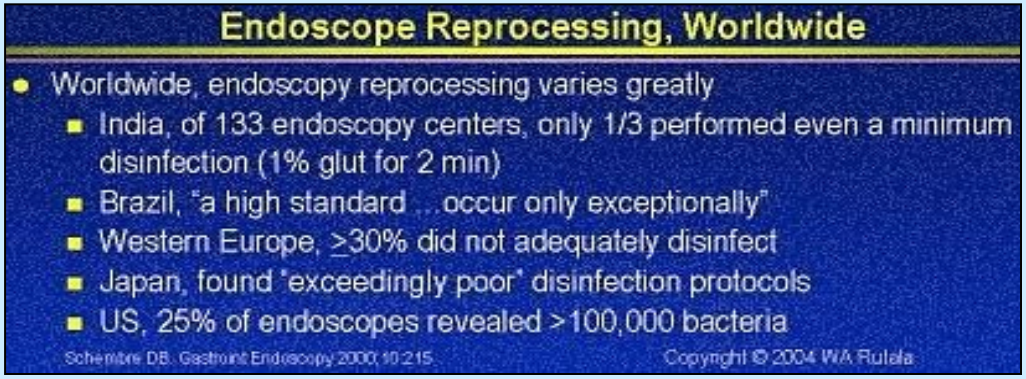
As guilty of CI risk are named doctors and nurses, however problem's analysis showed that it is not so.

Gastrointestinal endoscopes transmit more than 390 infections [3], among which HIV, hepatitis B and C viruses; there are described group disease cases. Pioneer in these endoscopes' manufacturing is Japan; probably it's why in 2006 there were almost 3 mln infected with hepatitis C virus – 2,3% of population [4]?

Hepatitis C is a cross-infection with threat of cirrhosis and, probably, hepatic cancer. In common, CI consequences are very difficult to be revealed and assessed - clinic may appear months or years later but, likely, not everytime. Despite it, the basic requirements of medicine do not allow disregard the risk of CI: the world is increasingly talking about crimes against humanity, but what is concealed infectioning of millions of people?

2. Business and risk of CI

Flexible endoscopes is a $2,5 billion market growing at an average 8-10% annually; the automated endoscope reprocessing is a $1 billion market growing at 10-12% annually [5]. Analysis of first 3 decades of flexible endoscopy revealed the general inadequate high-level disinfection (HLD). Here are corresponding data by W.A. Rutala [3].



The last 10 years not only does not reduced CI risk [6-12], but transformed it into misleading business and financial burden for medicine: while creating and selling very expensive washing-disinfection machines, cabinets for endoscopes' storage, transportation containers, manufacturers ignore 3 indisputable facts:

1) the main obstacle to adequate HLD is an inadequate design of endoscopes,
2) HLD adequaticy is defined not by machine, but by manual brushing of endoscope,
3) chain "machine-cabinet-container" has a risk of secondary infectioning of endoscope.

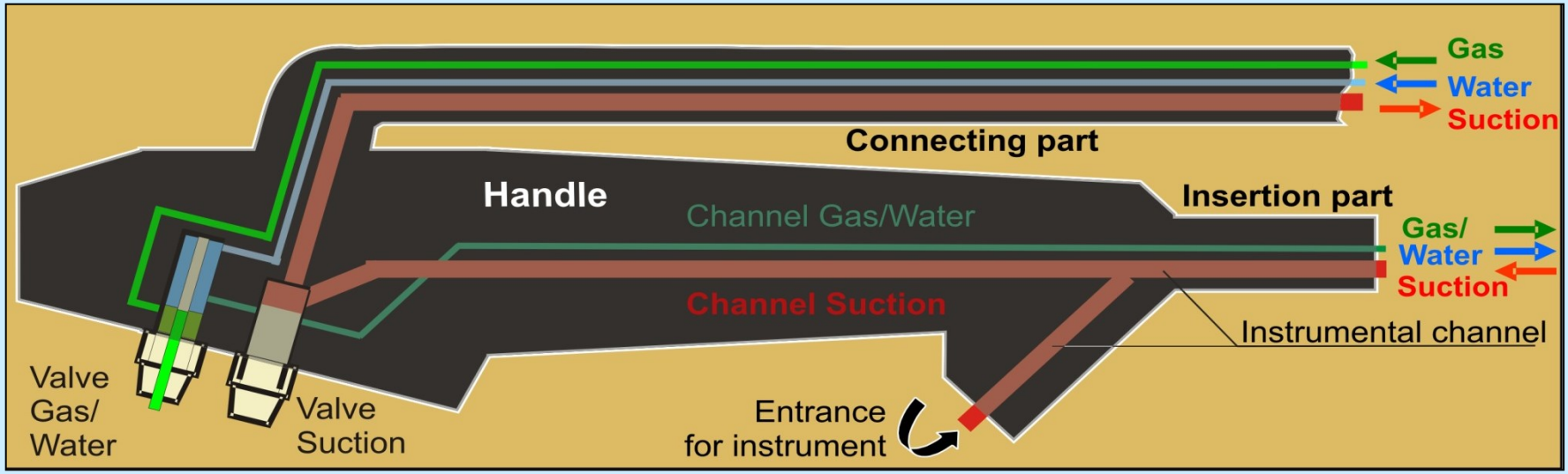
Thus, CI is the scaled, concealed everywhere except the USA and Canada, problem (see slide 12). Organisers of medicine ignore top-reasons of CI and obtain dangerous equipment, that can lead to dramatic consequences for each of us.

3. Multi-channel endoscope

According to E.Spaulding biopsy forceps and other instrument which penetrates mucosa, are critical items; flexible endoscopes are semi-critical ones, as their separate zones anyhow are in contact with mucosa, mucus, contents. Instrument could be sterilized by high temperature, flexible endoscopes could treat only cold HLD.

In the multi-channel endoscopes there are minimum 12 contact, or more exactly – semi-critical zones, which require manual brushing. These are:

- 2 channels of insertion part, nozzle of objective,
- segment of Suction channel, located in a handle; 2 valves, their shafts,
- 3 channels of connecting part, its connector.



Scheme of multi-channel endoscope

4. What creates the risk of CI

1. Zones which require manual brushing. As more they are, and as less they are accessible – the higher is CI risk. The old endoscopes have not less than 12 such zones.
2. Large length and small diameter of channels. Channels of old colonoscopes reaches 7,5m, of gastroscopes - 6,5 m. Channels with diameter 3-4 mm are cleaned by manual brushes, the small ones (with diameter 1,2 mm) are flushed by liquid flow, however the biofilms formed therein [13] require manual brushing of all channels [14].
3. Non-hermecity of endoscope. Infection, which penetrated inside the device, could become a source of group infection.
4. The chain "machine-cabinet-container". The existing system of disinfection, storage and transportation of old endoscopes has a risk of their secondary infection:
   - 4.1. Sterilization of chain's parts is impossible and disinfection is difficult. In this regard there could be breeded infection from endoscopes, which were there before.
   - 4.2. At junction of chain's parts endoscopes are contaminated by hospital infection.
   - 4.3. Open device's storage allows next endoscopy during 3 hours after HLD, at storage in special cabinet - during 3 days. Whether these conditions could be compared with storage of disposable means!
5. Infectioning of population. In connection with factors 1-4 and this one, the risk of infection by hepatitis C virus, for example in Egypt is 36 times higher, than in Italy [4].
6. Traumacity of endoscopy. Abrazions and microtrauma of mucosa which inevitably follow endoscope's insertion, as well as biopsy and other endoscopy operations, in combination with factors 1-5, increase the CI risk.

5. Base of Aseptic method of infection safety of colono- and gastroscopy

Risk of CI by disposable means is everywhere close to 0. In Western Europe ≥*30% of endoscopes are disinfected inadequately, in the USA in 25% of endoscopes are revealed more than 100.000 bacteria* [3]; in other regions the risk is higher.

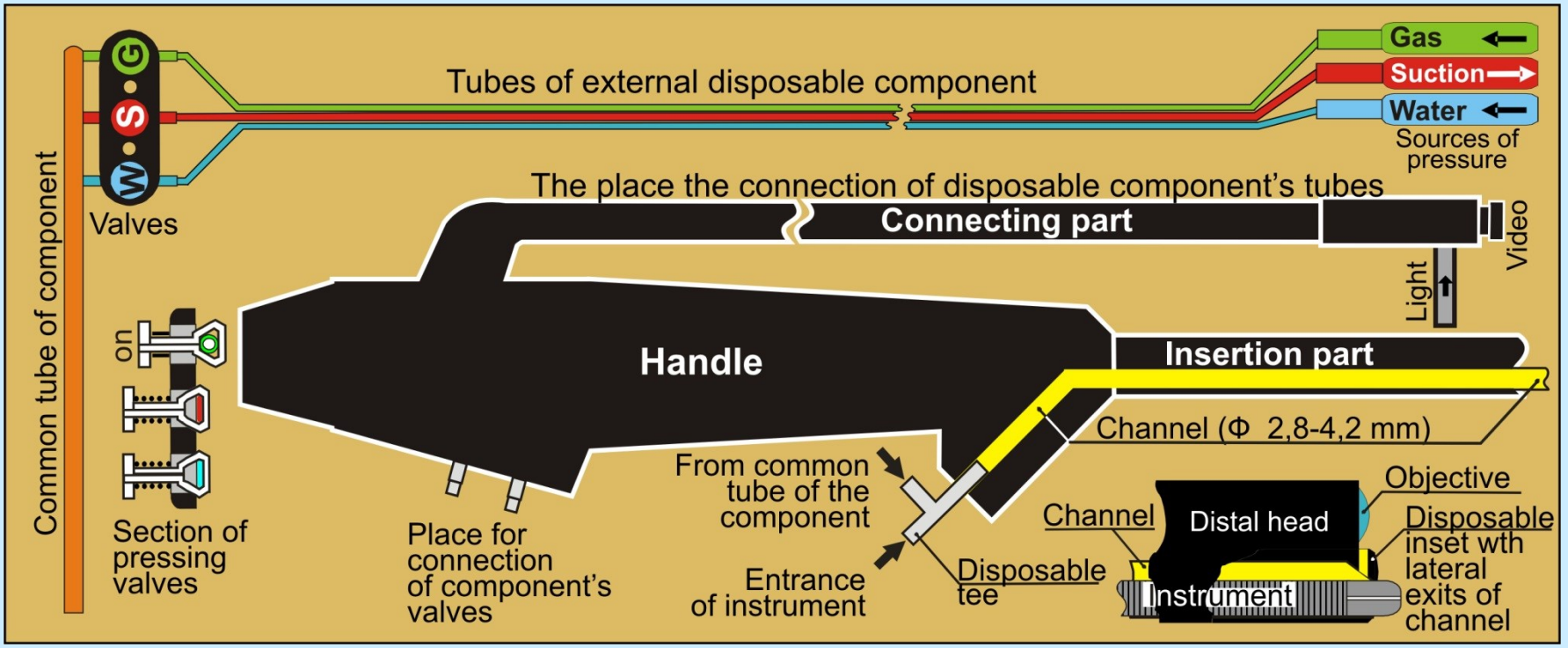
Disposable flexible endoscopes are very expensive; alternative to them, to multi-channel endoscopes at all, disinfection machines, cabinets, transporting containers is the Method proposed. It is based on 2 inventions:

1. "Endoscope with single-channel endoscopic tube and disposable set which connects channel with pressure sources" (patents of Latvia, China, Japan [16, 17, 18]; applications in the UK, EAPO, USA, DE). Technical effect of invention - minimization of zones, which require manual brushing.
2. "Aseptic method of HLD, storage and transportation of a flexible endoscope and device for its implementation" (patent of Latvia [19], application PCT [20]). Technical task of invention - replacement of three-part chain "machine-cabinet-container" by a single device.

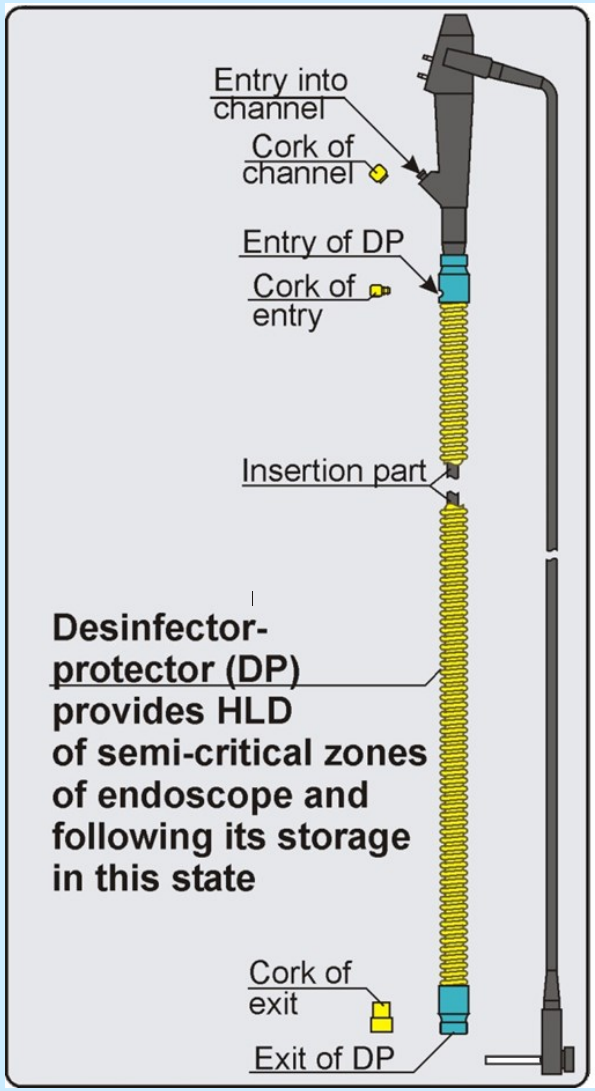
6. 1-channel endoscope

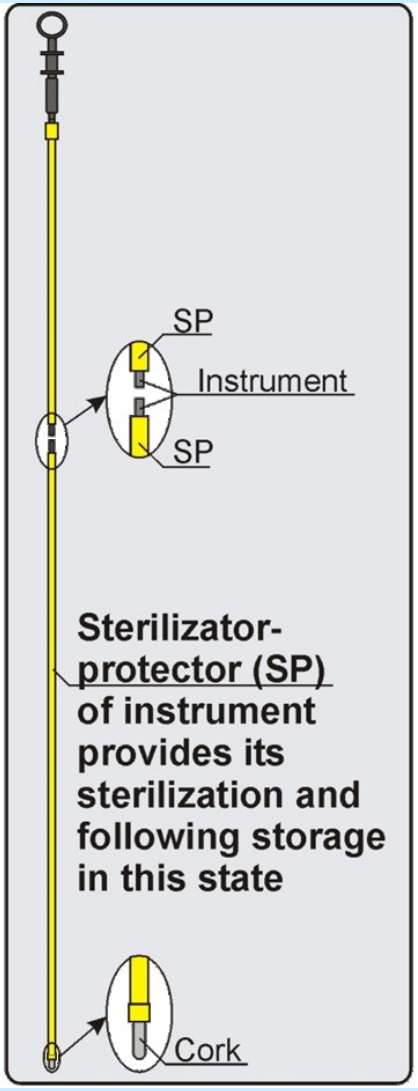
The new endoscopic tube has not valves and has only 1 channel which connects with 3 tubes of external disposable component with the help of pressing valves and tee. The channel, 3 tubes, their valves, tee provide supplying of gas and water, evacuation of contents; for washing of 3 lenses at the end of channel there is disposable inset with 3 lateral outputs, at that the direct output should be closed by the end of instrument.

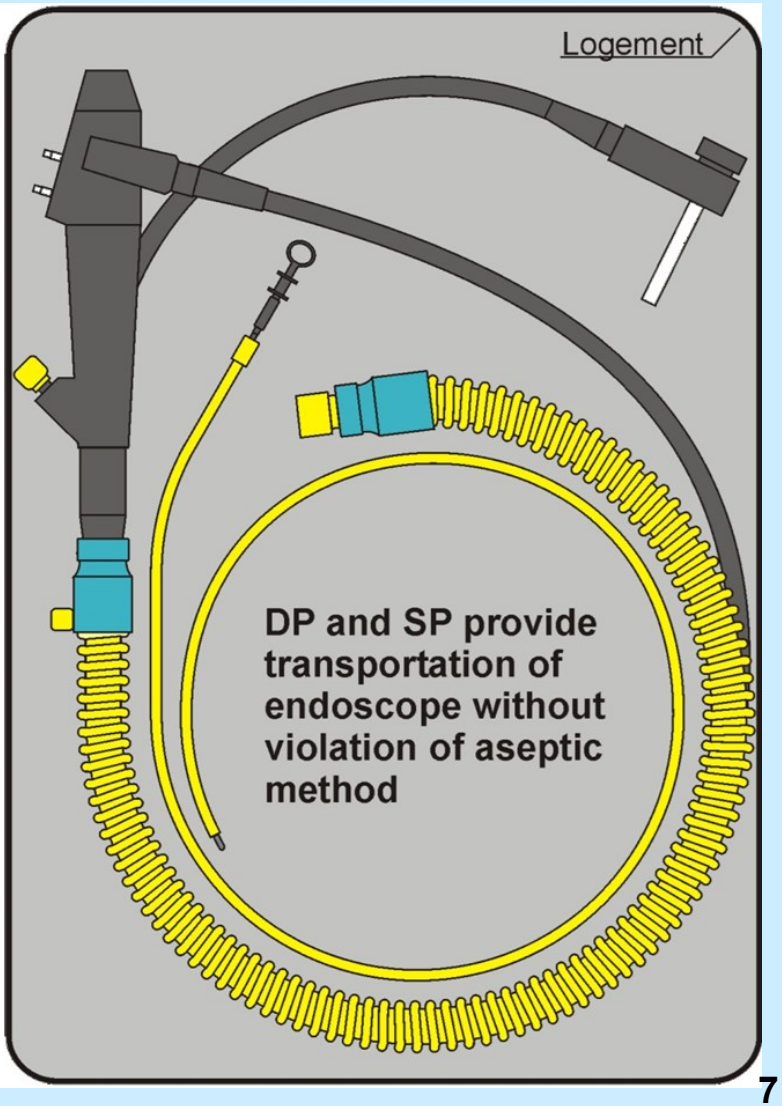
Thus, new endoscope has only 2 semi-critical zones: sheath and channel of insertion part; manual brushing is required only the channel with diameter is 3-4 mm, length – 1 m or 1,6 m.



7. Illustrations to the method of HLD, storage and transportation of 1-channel endoscope







8. Comment to the method of HLD, storage and transportation of new endoscope

The optimal variant of reprocessing of 1-channel non-valve endoscope supposes 4 stages:

1. Pre-cleaning.
2. Thorough cleaning-disinfecton of all surfaces of endoscope.
3. HLD of sheath and channel of the insertion part.
4. Hermetization sheath and channel of the insertion part.

The 1st and 2nd reprocessing stages are made as usually, the 3rd stage uses disenfector-protector (DP) in the shape of sterile corrugated silicone tube (see on slide 7), putted on the insertion part. The 3rd stage requires only about 0.2 l of disinfectant. Following the washing and drying of sheath and channel of the insertion part as well as DP cavity, the 4th stage is to be realised – hermetization of semi-critical zones by sterile corks (see on slide 7).

Thus DP ensures high-level disinfection of semi-critical zones of single-channel non-valve endoscopic tube, their long-term storage and transportation in HLD state.

The method of sterilization and storage of biopsy forceps is similar to the described above. After cleaning-disinfection, the forceps are sterilized together with silicone tube, which hermetizes its insertion part and is called sterilizer-protector (SP) – see on slide 7.

9. Differences of the Aseptic method of infection safety of colono- and gastroscopy

As not all channels of multi-channel endoscopes are acessible to manual brushing, but equipment for disinfection, storage and transportation of endoscopes is not accessible for sterilization, the existing method of infection safety of colono- and gastroscopy could not be concerned as an aseptic.

1-channel non-valve endoscope reduced:

1.1. total number of zones which require manual brushing from 12 to 1,

1.2. number of valves and their shafts, requiring manual brushing, from 4 to 0,

1.3. number of channels, which require manual brushing, from 6 to 1,

1.4. number of channels, inaccessible for manual brushing, from 3 to 0,

1.5. length of channels of colonoscope from 7,5m till 1,6m, of gastroscopes from 6,5m till 1m,

1.6. diameter of the insertion part of endoscopic tube.

Disinfector-protector of semi-critical zones of 1-channel non-valve endoscope:

2.1. could be sterilized,

2.2. excluded secondary contamination of semi-critical zones,

2.3. significally longer saves semi-critical zones in the HLD state,

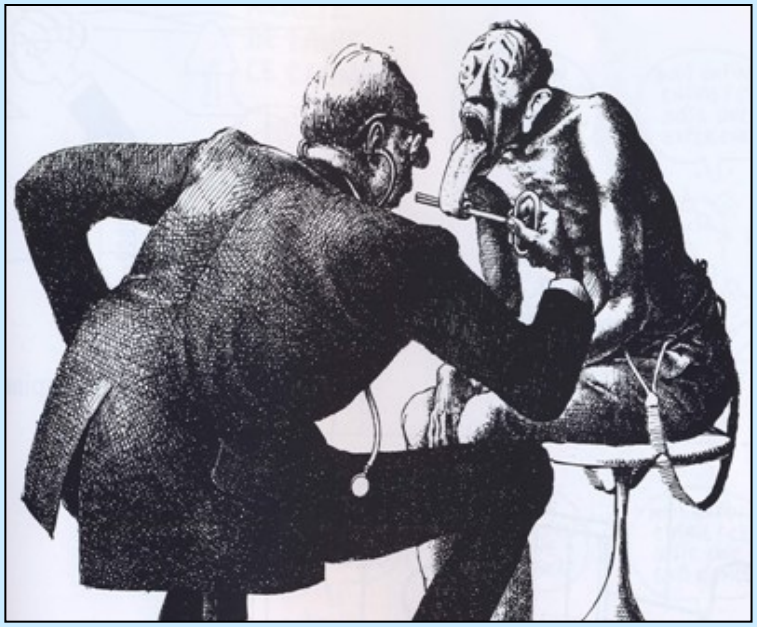
2.4. reduced equipment price up to thousand times – till € 40,

2.5. reduced amount of disinfectant and sterile water to dozens times,

2.6. does not require premises.

10. Conclusion

1. Inadequate HLD of multi-channel endoscopes is a result of their inadequate construction. Namely for this reason washing-disinfecting machines did not improve situation with CI: ECRI forecasts that in 2014 CI risk will displace from 8th to 6th place.
2. The proposed Method reduced from 12 till 1 the number of endoscope's zones, which require manual brushing, and till 2 - the common number of semi-critical zones; provided its HLD, storage and transportation in a sterilized tube, which has the small price.
3. The substitution of dangerous endoscopic technique will be defined by legal motivation of its manufacturers.



One more alternative to gastroscopy. ☺ .
Interpretation of Claude Serre sketch.

11. Basic sources of information

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13. *Enclosure 1:* 2013 year's data about risk of CI from Lawrence F. Muscarella, PhD [15]

- From January 02, 2013. US Air Forces Veteran and his wife has won the lawsuit of **$750.000** and **$500.000** against federal government – The court satisfied that the veteran contracted hepatitis C after a colonoscopy. http://www.myajc.com/news/news/456-piedmont-patients-warned-about-improperly-clea/nXckK/?icmp=ajc_internallink_invitationbox_apr2013_ajcstubtomyajcpremium
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- From July 18, 2013. About **900 patients**, who underwent gastro- or colonoscopy, received letters that they are at risk of infection. California. USA. http://www.ksbw.com/news/central-california/salinas/natividad-medical-center-sends-letter-to-patients-about-possible-infection/-/5738906/21036650/-/4u05y9z/-/index.html
- On November 5, 2013 Lawrence F. Muscarella reminded about **200 patients,** who sued the West Pensylvania hospital, where they affected the CI risk after colonoscopy http://app.expressemailmarketing.com/get.link?linkid=5965292&subscriberid=430335583&campaignid=1632098&linkurl=http%3a%2f%2fwww.myendosite.com%2farticles%2fForbesComplaint.pdf

14. *Enclosure 2:* 2014 year's data about risk of CI from Lawrence F. Muscarella, PhD [15]

Data about risk of CI in USA and Canada - only over-water part of iceberg, there are no anajogic publications in EU, others parts of the world. But whether American and Canadian data is insufficient to understand, that guilty in regular mass CI risk are not medicals, but manufacturers of endoscopic equipment and managers, who approved it? Who is guilty in accidents – driver or manufacturer of automobile with defective construction? Stabile dangerous situation with CI requires replacement of world park of colono- and gastroscopes, but this requires juridical motivation of Japan monopolies: Olympus, Pentax, Fujinon, who define the endoscopic paradigma.

From January 23, 2014. Canada, Ontario. **2 patients infected by Hepatitis C** on May 20 and November 8, 2013. Reason of infection is not known yet; techniques of cleaning and sterilization, as is informed, were duly implemented. http://www.bchsys.org/hospital/services-list/infection-control/endoscopy-ambulatory-care-investigation

Main
Back

15. *Enclosure 3:* Key details, bundles and aspects of the Aseptic method

(click on photo to enlarge it)


1. Disposable bottles Suction, Gas/Water


2. Disposable tee of entrance into channel


3. Disposable tubular component with valves


4. Disposable inset for channel's exit

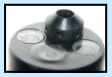

5. Disposable obturator of straight exit of inset


6. Handle of single-channel endoscope, view on supports of valves


7. Handle of endoscope; entrance into channel


8. Handle with component and tee


9. Tip of endoscope; exit of channel is free


10. Tip of endoscope; exit of channel occupied by inset


11. Entrance into channel is closed by obturator


12. Straight exit of inset is closed by obturator


13. Straight exit of inset is closed by forceps


14. Connector; view on core of light-bundle


15. Connector, view on nest of Processor cable


16. Connector; core of light-bundle is in block Light


17. Connector is connected with Processor cable


18. Cork of the nest of Processor cable


19. Preparation to the hermecity test


20. Hermecity test


21. Complete cleaning-disinfection


22. Disinfector -protector (DP)


23. HLD, flushing, drying of channel, sheath of insertion part and cavity of DP


24. Hermetization of channel, sheath of insertion part and cavity of DP; entrances of channel and DP are closed by sterile corks


25. Hermetization of channel, sheath of insertion part and cavity of DP; DP exit is closed by sterile cork