The Research and Application of Disposable Sheath for Preventing Digestive Endoscopy Cross-infection

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Because of the important features of digestive endoscope, it cannot be replaced by other methods in gastroenterology department.

The digestive endoscope is made of high polymer and electronic components, and there is a thin long polluted tube in the endoscope, so high level disinfection effect is not stable.
To improve disinfection stability, cleaning and disinfection should be with strict management system and quality control

**Strict management system**

- Job training of staff
- Training system of staff—
  - Staff protective measures
- Device management system
  - device checking, device overhaul, maintenance, cleaning and disinfection, sterilization device, emergency plan of malfunction, emergency plan of chemical leak

**Quality control**

- Endoscope cleaning, disinfection, sterilization standard operating procedure and quality monitoring standard
- Endoscope processing procedure and quality evaluation standard

Quoted from: Zhang Qing, Peking Union Medical College Hospital
Flexible endoscope recycling process

Pre-processing → Leak detection → Pre-cleaning → Enzyme wash → Rinsing

Clinical staff → Disinfection room or processed by CSSD staff

Use → Storage → Drying → End rinsing → Dinsinfection

After use: pre-processing leak detection → Lid waterproof cover, put the endoscope in the proper container, and send it to disinfection room or CSSD
All the disinfection machines and disinfectants cannot meet the demand of safety, quick, convenience and low-cost simultaneously.

<table>
<thead>
<tr>
<th></th>
<th>Disinfection effect</th>
<th>Toxicity to human</th>
<th>Corrosiveness to metal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glutaraldehyde</strong></td>
<td>A</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td><strong>Orthophthalaldehyde</strong></td>
<td>A</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td><strong>Electrolyzed acid water</strong></td>
<td>D</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td><strong>Sodium hypochlorite</strong></td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td><strong>Hydrogen peroxide</strong></td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
</tbody>
</table>

A: good; B: mild toxicity; C: bigger toxicity, do not recommend using; D: easy to decompose, influence the effect
Current high level disinfection may cause unstability as follows:

① Halfway cleaning;
② The disinfection is insufficient, the endoscope is not disinfected;
③ Disinfection time is not enough;
④ The disinfection of accessories cannot reach the requirement;
⑤ The cleaning and drying after disinfection is not enough;
⑥ Cross-infection in processes;
⑦ Water pollution;
⑧ Disinfection device is used in a wrong way;
⑨ The forming of biofilm
The scratches in the endoscope and forming of biomembrane
The severity of forming biofilm

Society of Gastroenterology Nurses and Associates appointed:

**Once the biofilm has been forming in the endoscope channel, it is hard to be removed even if you use right cleaning and disinfection methods. At present, it is thought that biofilm forming is one of the endoscope cleaning and disinfection failure reasons.**

When the instruments goes in and out the flexible endoscope, a certain amount of microflora may be in the scratches, and it will become biomembrane in water and disinfectant gradually. The biofilm attaches firmly, and is permanent damage.
Infection transmission of endoscope

HP, HBV, HCV, even HIV and mad cow disease can be transmitted in endoscopy, medical community, patients and media have paid attention to this problem.

In 1993, American Society of Digestive Endoscope (ASGE) stated that incidence rate of endoscopy infection is 1:1,800,000. But in fact, the real infection rate is far more than the number, especially in undeveloped countries and regions.

According to the report of Chinese Journal of Disinfection, the Fourth Military Medical University carried out 161 cases random check to one affiliated hospital, 32 cases of total bacterial count is out of limits, it is 19.9%

In addition, the infection consequence cannot be found in a short time, it is hard to be held accountable, so medical department give little attention.
The idea of "disposable" appeared

To all the medical instruments, the best way of preventing infection is being disinfected and disposable use. But endoscope is expensive, it usually cannot be used as a disposable device.

So people did some research on using disposable consumable material to separate the endoscope from patient's cavity. This method makes the reusable endoscope to realize the preventing effect of one person one endoscope.
The patents of endoscope disposable sheath

In 2004, the quantity of endoscope disposable sheath patents application is 1400 in the world.

the patents of main companies

<table>
<thead>
<tr>
<th>Companies</th>
<th>flexible endoscope sheath patents</th>
<th>rigid endoscope sheath patents</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>奥林巴斯株式会社</td>
<td>158</td>
<td>26</td>
<td>1990 till now</td>
</tr>
<tr>
<td>オリンパス株式会社</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>美国视科公司 Vision Sciences Inc.</td>
<td>11</td>
<td>12</td>
<td>1995 till now</td>
</tr>
<tr>
<td>宾得株式会社 パンタックス株式会社</td>
<td>41</td>
<td>16</td>
<td>2003 till now</td>
</tr>
<tr>
<td>豪雅Hoya株式会社</td>
<td>2</td>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>史赛克公司 Stryker GI Ltd</td>
<td>19</td>
<td></td>
<td>2006—2008</td>
</tr>
<tr>
<td>以色列视线技术公司 SIGHTLINE TECHN LTD</td>
<td>6</td>
<td>1</td>
<td>2000—2007</td>
</tr>
<tr>
<td>富士能公司（美国） Fujinon Inc.</td>
<td>1</td>
<td></td>
<td>1988</td>
</tr>
<tr>
<td>辽宁省内窥镜工程研究中心 Shenda Endoscope Ltd</td>
<td>23</td>
<td></td>
<td>2002-2011</td>
</tr>
</tbody>
</table>

Data quoted from: www.prior-ip.com
Vision-Sciences Company produced a kind of disposable sheath named "Endosheath" according to its patents. This product made a historical breakthrough. The endoscope is "D-shaped", it is convenient for changing instrument channel, but the D-shaped endoscope is not flexible for turning.
Stryker Company cooperates with Sightline Technologies Ltd., and made the advertisement of colonoscope with disposable sheath, and proposed a new structure. But they did not promote the disposable sheath.
We spend ten years on this research, the structure is as follows:
1—endoscope, 1.1—the front end of endoscope 1.2—light guide part, 1.3—operating portion biopsy channel, 1.4—suction valve seat 1.5—water/air valve seat

2—insertion portion sheath, 2.1—sheath, 2.2—locking ring, 2.3—end cover of sheath, 2.4—disposable forceps channel, 2.5—water/air tube connector, 2.6—water/air tube 2.7—one-way valve

3—three-way sealing cap, 3.1—front suction tube, 3.2—heat seal hole, 3.3—instrument insertion opening connector

4—suction valve, 4.1—back suction tube 4.2—suction tube fixing clip, 4.3—suction machine connector, 4.4—suction valve connector

5—operating portion sheath, 5.1—instrument insertion opening, 5.2—left hand entrance
The back end of disposable sheath is protected specially.
The disposable sheath has been checked and doing clinical in designated units according to national requirements.
Registration certificates

医疗器械注册登记表

注册号：辽食药监械（准）字2007第2660052号

生产企业名称：沈阳沈大内窥镜有限公司

企业注册地址：沈阳市新民市三好街35号

生产地址：沈阳市大东区联合路176号

产品名称：内窥镜一次性使用护套

型号、规格：QVME-98型、QVME-1300型、QGIF-V70型、QCFIT140L/I型

产品标准：YZB/辽0459-2006 内窥镜一次性使用护套

产品性能结构及组成：

产品性能指标：

1. 分离率：在工作距离16mm处，分离率与未装护套相比，应不低于其分离率的2.5倍以上。

2. 透光性：在工作距离10mm处，透光度应不低于未装护套的80%。

3. 送水流量：应不小于45ml/min。

4. 头部结构强度：应不小于未装护套的80%。

5. 弯曲性能：应不大于15°/g/eg。

产品适用范围：

*本品为内窥镜防护用品，用于预防交义感染。

产品禁忌症：

对天然胶乳橡胶等高分子材料过敏者禁用。

备注：

注：二〇〇七年五月十日
Academic paper & media reports:
The new member of mobile medical

- Convenient for carrying, improving the endoscope mobility
- can be used in any conditions
- no need large disinfection devices and space
- no need water and electricity, and no waste water
Beijing Military General Hospital use the disposable sheath for border soldiers
Beijing Military General Hospital medical team went to more than 80 border units from 2010 to 2012. They did 1,120 cases gastroscopy, 23 cases colonoscopy. The result is as follows:

<table>
<thead>
<tr>
<th></th>
<th>Gastroscope</th>
<th>Colonoscope</th>
<th>Obvious lesion (gastroscope)</th>
<th>Detection rate (gastroscope)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group with sheath</td>
<td>568</td>
<td>11</td>
<td>221</td>
<td>38.9%</td>
</tr>
<tr>
<td>Control group</td>
<td>552</td>
<td>12</td>
<td>239</td>
<td>43.3%</td>
</tr>
</tbody>
</table>

Quoted from Beijing Military General Hospital
The features:

(1) The preventing infection effect is close to sterilization level;

(2) It is sterilized consumable material, and packed in a small package. It's convenient for carrying, improving the endoscope mobility. It is the method for gastroenterology doctors being added in mobile medical team;

(3) It only costs 5 mins to put on and take off the disposable sheath. It saves disinfection time, improves efficiency, accelerates turnaround, prolongs endoscope life and reduces endoscope quantity;

(4) Energy saving and emission reduction There is no need large amount of water and electricity and no medical waste water;

(5) Preventing prion transmission in endoscopy. The maximum pore space of disposable sheath is 6.72nm, it is less than prion length.
Contraindication & the existing problems

Contraindication:
The patients with upper gastrointestinal varication are prohibited to use the disposable sheath.

The existing problems:
1. The endoscope insertion portion is covered by film, so it may be a little inconvenient for patients;
2. The transparent film covers the object lens, it may influence the transparency slightly;
3. Because the disposable forceps channel inserts into the normal endoscope, the diameter of endoscope forceps channel will be smaller. There will be no problem for diagnosis, but may influence the operation. So we would like excellent flexible endoscope manufacturers to support and make the diameter of forceps channel larger about 0.5mm. Both of us provide full performance and safe flexible endoscope for patients.
Thanks