Instruction for Use of Disposable Endoscopic Cytology Brush

JS-CE-SM-06-01, A/0
Instruction for Use of Disposable Endoscopic Cytology Brush

【Product name】
Disposable Endoscopic Cytology Brush

【Product structure and components】
Disposable Endoscopic Cytology Brush consists of brush (nylon), sheath (PTFE), pulling wire (06Cr19Ni10) and handle (ABS). It can be divided into several specifications according to channel ID, working length and brush shape. The product should be sterile.

【Specification】

<table>
<thead>
<tr>
<th>Specification</th>
<th>Endoscope channel ID code</th>
<th>Working length L(mm)</th>
<th>Brush shape</th>
</tr>
</thead>
<tbody>
<tr>
<td>C(E,K,N,Q,T,U, V,LK）-A（B）</td>
<td>28: Channel ID ≥2.8mm</td>
<td></td>
<td>B: U-shape brush</td>
</tr>
</tbody>
</table>
【Packaging list】
Inner package: Paper-plastic bag, 1 pcs/bag
Middle package: Paper box, 1pcs/box
Outer package: Corrugated box

【Intended use】
Clinically used to brush cell samples. Sterile, for single-use.

【Contraindication】
None.

【Notice】
1. The product should be operated by professionals after reading the instruction carefully.
2. The doctor should be gentle when operating. Do not force too hard.
3. Do not use the instrument when the package is damaged.
4. The product should be used immediately after opening the package.
5. Single use only, discards after use. Do not reuse.
6. Do not use the instrument when the valid period is exceeded.
7. The brush should be took back into the sheath after sampling. Make sure the cell will not fall off when retreat the brush.

【Usage】
1. Choose an appropriate cytology brush according to working channel. The sheath OD should be smaller than channel ID, and the working length should be longer than endoscope itself. The
sheath should be of no crease and the brush head should be of no damage. Try to operate the brush that it can get in and out of the sheath smoothly. Please prepare spare cytology brush in case of accident.

2. Under the inspection of endoscope, slowly move the brush for 2-3cm each time. Move the brush to the sampling position.

3. Brush back and forth for 4-5 times on sampling position. After sampling, withdraw the brush into sheath and then retreat the cytology brush from working channel.

【Expiration date】
The product will be valid for 3 years. For specific production date and expiration date, please see product labels.

【Sterilization】
Sterilized by ethylene oxide.

【Storage & Transport】
1. The instrument should be placed in the environment with relative humidity of less than 80% and without corrosive gas. Store the device at cool, dry, clean room of good ventilation.

2. Do not store the sterile instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could pose a risk of infection control or cause infection in affected part of patients.

3. The inner package is paper-plastic bag, middle is the box, and
outer is the corrugated carton. Transportation should maintain clean, dry and sealed.

4. Transportation conditions: It should prevent stress and could not be transported together with sand, metal fragments, glasses or keen-edged stuff, nor with the poisonous, corrosive or flammable stuff. Slinging of packages when loading and unloading, insulation under the sun or drenching in rain are all prohibited.

【Signs & Symbols】

<table>
<thead>
<tr>
<th>Icon</th>
<th>Meaning</th>
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<tbody>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Disposable</td>
</tr>
<tr>
<td><img src="image" alt="adastro" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Do not use when the package is damaged</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Lot number</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>EU representative</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>CE certified by TUV SUD</td>
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<thead>
<tr>
<th>Icon</th>
<th>Meaning</th>
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</thead>
<tbody>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Sterilized by EO</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Expiration date</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Read instructions before use</td>
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<td><img src="image" alt="廞" /></td>
<td>Note that see instruction for use</td>
</tr>
<tr>
<td><img src="image" alt="廞" /></td>
<td>Manufacturer</td>
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</tbody>
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Compile date: 2015.08.08
【Validity Period】3 years
【Manufacturer】Jiangsu Changmei Medtech Co., Ltd.
【Registered Address】
No. 27 Xinke West Road, Luoyang, 213104,
Changzhou, Jiangsu, China
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【Tel】0086-519-88520118
【Fax】0086-519-88551179
【Website】http://www.czmed.com
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