

## ハイリスク手術に用いた手術器械の処理方法 (案)

2007年11月18日 小林寛伊

文献に裏づけされた不活性化処理方法<sup>10, 11, 14, 19)</sup>

1. 適切な洗剤による十分な洗浄 + SDS 処理<sup>9, 12, 14, 16, 17, 22)</sup>  
 (血液などの汚染を除去しないと後で固まって落ちなくなるので事前洗浄が必要)  
<sup>9)</sup>: 5% SDS 70°C ≤ 1hr  
<sup>12)</sup>: 引用文献なし  
<sup>14)</sup>: Efficacy of 5% SDS is confirmed. Thus association of SDS & NaOH may be of interest, but more tests both *in vitro* and *in vivo* must be performed.  
<sup>22)</sup>: Variably or partially effective
  
2. アルカリ剤<sup>\*</sup> washer disinfectant 洗浄(90-93°C) + 134°C、8~10分<sup>2, 3, 5, 6, 14, 21, 24)</sup>  
<sup>21)</sup>: Detergent with enzyme before disinfection is essential.  
<sup>24)</sup>: 2/9 infected.
  
3. **Washer disinfectant** が用いられない場合  
 適切な洗剤による十分な洗浄  
 + 高圧蒸気滅菌(プリバキューム式)134°C、18分<sup>1, 2, 4, 5, 6, 7, 8, 9, 13, 14, 15, 18, 20, 21, 22, 23)</sup>  
 (洗浄: 4-log<sub>10</sub> reduction + 高圧蒸気滅菌: >2~3-log<sub>10</sub> reduction  
 = 6~7-log<sub>10</sub> reduction)  
<sup>5)</sup>: Not to be reliably effective for removal. However, autoclaving still remains an important method of reducing infectivity.  
<sup>6)</sup>: 繰り返し効果なし  
<sup>7)</sup>: 132°C (gravity) 1hr  
<sup>15)</sup>: 132°C (gravity) 30min  
<sup>18)</sup>: 134-138°C (porous-load) 無効  
<sup>22)</sup>: In worse-case scenarios (brain tissue baked-dried on to surfaces) infectivity will be largely but not completely removed.  
<sup>8, 26)</sup>: 8) で 134°C、18 分に条件(水中での高圧蒸気滅菌)をつけていたが、最近の報告<sup>26)</sup>では、無条件で、134°C、18分 prevacuum 方式(porous load cycle)の RF を 4-4.5 (Hamster 263K)、≥5.5 (Mice 6PB1) - WHO1999 勧告の方法

4. アルカリ洗剤洗浄(洗浄温度はメーカー指示に従う)

+ 過酸化水素ガスプラズマ滅菌 2 サイクル <sup>24, 26)</sup>

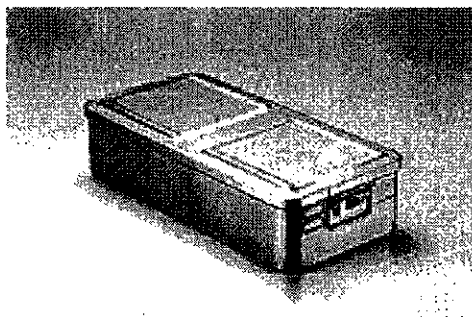
(軟性/硬性内視鏡、一部 loan instrument に対しては、これ以外に方法がありません)

<sup>26)</sup>: アルカリ洗剤、1.6v/v%、43°C、15 分浸漬、および、0.8v/v%、43°C、7.5 分浸漬で、RF ≥ 5.5 を得ている

【参考資料】

使用済み手術器械搬送回収用コンテナの例示(SDS 煮沸にそのまま使えないか?)

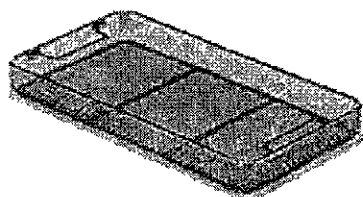
- リムーバルコンテナ  
002-330-50 = 002-330-40(蓋) + 002-330-30(底) = ¥59,800 + ¥73,200 = ¥133,000.-
- バスケット 002-318-70 = ¥40,700.-



リムーバルコンテナ (回収用)

- リムーバルコンテナは、使用済み器材を密閉して回収する専用容器です。
- リムーバルコンテナはステンレス製のため薬剤浸漬も可能で、耐腐食に優れています。

品番	型番	寸法
002-328-25	JF082R	L295×W280×H150mm
002-331-50	JF282R	L586×W280×H150mm



ワイヤーバスケット (フルサイズ用)

品番	型番	寸法
002-318-40	JF672R	L485×W254×H 25mm
002-317-45	JF499R	L485×W254×H 50mm
002-318-45	JF674R	L485×W254×H 70mm
002-317-50	JF500R	L485×W254×H100mm
002-318-65	JF688R	L540×W254×H 30mm
002-318-70	JF690R	L540×W254×H 50mm
002-318-75	JF692R	L540×W254×H 70mm
002-318-80	JF694R	L540×W254×H100mm

## 文献

1. AORN. *2006 Standard, Recommended practices, and Guideline*. Denver: AORN 2006.
2. APIC. *APIC Text of Infection Control and Epidemiology* 2<sup>nd</sup> ed. Washington DC: APIC 2005.
3. Baier M, Schwarz A, Mielke M. Activity of an alkaline 'cleaner' in the inactivation of the scrapie agent. *J Hosp Infect* 2004; 57: 80-84.
4. DH. *The decontamination of surgical instruments with special attention to the removal of proteins and inactivation of any contaminating human prions*. 2006 Report from ESAC-Pr. [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_072443](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_072443).
5. DH. *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection*. <http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm>
6. Economics, Statistics and Operational Research, Department of Health. *Assessing the risk of vCJD transmission via surgery : An interim review*. Mar 2005. [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4113541](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4113541)
7. Ernst DR, Race RE. Comparative analysis of scrapie agent inactivation methods. *J Virol Methods* 1993; 41: 193-202.
8. Fichet G, Comoy E, Duval C, et al. Noval method for disinfection of prion-contaminated medical devices. *Lancet* 2004; 364: 521-526.
9. Kimberlin RH, Walker CA, Millson GC, et al. Disinfection studies with two strains of mouse-passaged scrapie agent: guidelines for Creutzfeldt-Jacob and related agents. *J Neurol Sci* 1983; 59: 355-369.
10. 小林寛伊. 手術とCreutzfeldt-Jacob病. *感染制御* 2006; 2: 357-361.
11. National Institute for Clinical Excellence SCOPE\_020904. Patient safety and reduction of risk of transmission of Creutzfeldt-Jacob Disease (CJD) via surgical instruments. <http://www.nice.org.uk/niceMedia/pdf/smt/070904item5.pdf>
12. 中川正法. 変異型CJDとBSE. *松仁会医学誌* 2004; 43(2): 113-121.
13. Rutala WA, Weber DJ, the Healthcare Infection Control Practices Advisory Committee. *Draft*

- Guideline for Disinfection and Sterilization in Healthcare Facilities*. <http://hica.jp/cdcguideline/dsguide.pdf#search='hica.jp/cdcguideline/dsguide.pdf'>
14. SCENIHR. *The safety of human-derived products with regard to variant Creutzfeldt- Jacob disease*. [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_004b.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004b.pdf)
  15. Taguchi F, Tamai Y, Uchida K, et al. Proposal for a procedure for complete inactivation of the Creutzfeldt-Jacob disease agent. *Arch Virol* 1991; 119: 297-301.
  16. Tateishi J, Tashima T, Kitamoto T. Practical methods for chemical inactivation of Creutzfeldt-Jacob disease pathogen. *Microbiol Immunol* 1991; 35(2): 163-166.
  17. Tateishi J, Tashima T, Kitamoto T. Inactivation of the Creutzfeldt-Jacob disease agent. *Ann Neurol* 1988; 24:466-466.
  18. Taylor DM, Fraser H, McConnell I, et al. Decontamination studies with the agents of bovine spongiform encephalopathy and scrapie. *Arch Virol* 1994; 139: 313-326.
  19. WHO. *WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies*. World Health Organization 2006. <http://www.who.int/bloodproducts/TSEREPORT-LoRes.pdf>
  20. WHO. *Environmental Management Practices*. 2004. [http://www.who.int/water\\_sanitation\\_health/hygiene/envsan/infcontrolenv\\_mgmt.pdf#search='WHO.%20Environmental%20Management%20Practice'](http://www.who.int/water_sanitation_health/hygiene/envsan/infcontrolenv_mgmt.pdf#search='WHO.%20Environmental%20Management%20Practice')
  21. WHO. *Practical guidelines for infection control in health care facilities*. WHO 8 Dec. 2003. [http://www.wpro.who.int/NR/rdonlyres/006EF250-6B11-42B4-BA17-C98D413BE8B8/0/Final\\_guidelines\\_Dec2004.pdf#search='WHO.%20Practical%20guidelines%20for%20infection%20control%20in%20health%20care%20facilities'](http://www.wpro.who.int/NR/rdonlyres/006EF250-6B11-42B4-BA17-C98D413BE8B8/0/Final_guidelines_Dec2004.pdf#search='WHO.%20Practical%20guidelines%20for%20infection%20control%20in%20health%20care%20facilities')
  22. WHO. *WHO infection control guideline for transmissible spongiform encephalopathies. Report of a WHO consultation, Geneva, Switzerland, 23-26 March 1999*. <http://www.med.oita-u.ac.jp/infectnet/guideline.pdf#search='WHO%20infection%20control%20guideline%20for%20transmissible%20spongiform%20encephalopathies'>
  23. Winder AF, Frei R. Decontamination, disinfection, and sterilization. In: Murry PR, et al Eds. *Manual of Clinical Microbiology*, 8<sup>th</sup> ed. Washington DC: ASM 2003; 77-108.
  24. Yan Z, Stitz L, Heeg P, Pfaff E, Roth K. Infectivity of prion protein bound to stainless steel wires : A model for testing decontamination procedures for transmissible spongiform

encephalopathies. *Infect Control Hosp Epidemiol* 2004; 25: 280-283.

25. Rutala WA. Prion(CJD) and processing of reusable medical products. 2004 <http://www.unc.edu/depts/spice/dis/prions.ppt> (参考スライド)
26. Fichet G, et al. Investigations of a prion infectivity assay to evaluate methods of decontamination. *J Microbiol Methods* 2007; 70: 511-518.