

HNM

MEDICAL

EdgeHolder

INSTRUMENT PROTECTION SYSTEM

**PROTECT
ORGANIZE
COMPLY**



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HNM Medical is committed in providing surgeons and health care professionals with advanced surgical solutions for effective and time-saving treatment of their patients. Our most important task is meeting surgeons' needs. We accomplish this by creating key partnerships and driving innovative product development.

INTRODUCTION

HNM EDGE HOLDER

The HNM EdgeHolder Instrument Protection System (IPS) was designed by a leading university hospital to prevent costly damage to their delicate neuro instruments. After years of use and improvement, the system is now available to you.

You will be immediately familiar with the Edgeble Kimguard fabric that we use to form each EdgeHolder IPS.

HNM's unique pouch fabrication capabilities allow you to choose among one of our standard designs or customize a pouch to fit your specific requirements.

EdgeHolder IPS is not intended to provide a sterile barrier and should be used in conjunction with an outer wrap or container system.

EdgeHolder IPS can be used in your validated PreVac Steam Sterilizer. We recommend a minimum cycle of 270° F for 4 minutes exposure and 20 minutes dry time.

As with any product you use in your sterilization system, you should validate that it works in your system. Refer to ANSI/AAMI: St79 2006 for guidance.

CASE STUDY

The nursing and CS staff at a prominent university hospital stopped using paper instrument pouches in 1995. The hospital had unknowingly been compromising patient safety. Instruments were not sterile “We put a biological indicator in a pouch and tested it. We were not getting kills on the pouches and we realized that the steam was not getting through two layers of wraps.”

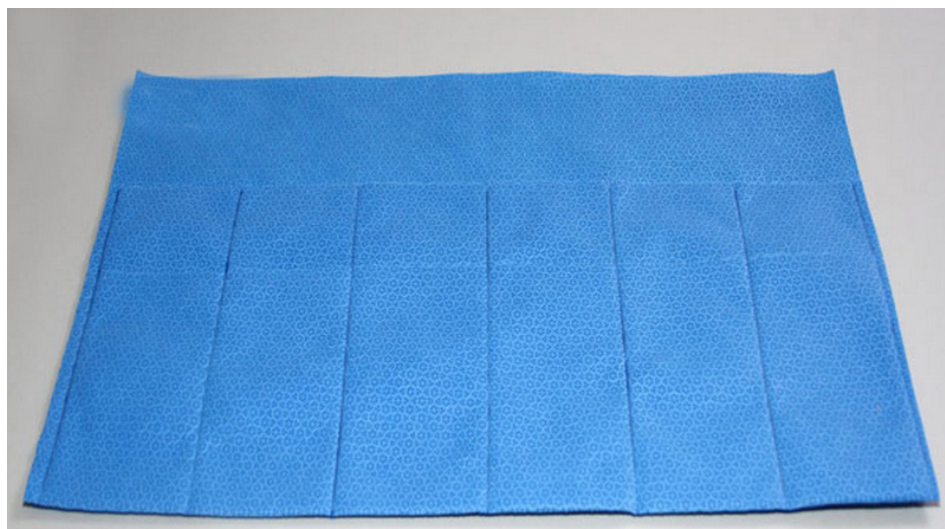
The facility stopped putting surgical instruments in peel pouches inside its trays and totally transformed the way it was sterilizing instruments. The hospital said, “There would have to be cases where instruments weren’t sterile.” After the staff made some critical changes, patient safety improved and the risk of non-sterile instruments was virtually eliminated.

These nurses and CS staff were ahead of their time but now hospitals around the country are catching up. Delicate surgical instruments have been sterilized in paper pouches within a tray for

years but this practice did not ensure patient safety. Nurses and CS professionals around the country have realized this error and are making some changes. As of July 2006, AAMI guidelines state that peel pouches should not be used inside of wrapped or containerized sets.

A portion of surgical instruments still pose infection risk after routine cleaning in hospitals. A 2006 study in the Journal of Hospital Infection showed that 17% of the surgical instruments tested at the point of use had unacceptable levels of residual protein and total organic matter, posing a direct infection risk. “It is inadvisable to use paper-plastic pouches within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, steam contact, and drying.

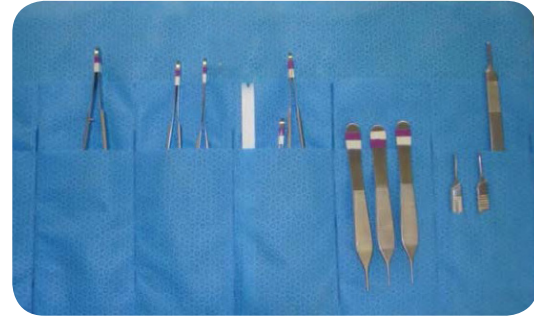
The practice of confining instruments in paperplastic pouches and then including them in wrapped or containerized sets (double-wrapping with dissimilar materials) has not been validated as appropriate and efficacious by any wrap, containment device, or paper-plastic pouch manufacturer.”



INDICATIONS FOR USE



Paper plastic pouch cannot be placed inside a rigid container and steam sterilized.



Paper plastic pouch was replaced with the Edgeholder to comply with AAMI-ST79, thereby protecting and organizing instruments.



The Edgeholder can be rolled up and placed in the rigid container.



STEAM STERILIZATION SYSTEM

INSTRUMENT PROTECTION SYSTEM

Steam sterilization Efficacy Testing Using HNM EdgeHolder Instrument Protection System (IPS)

Objective:

The objective of this study was to qualify the HNM EdgeHolder Instrument Protection System (IPS) family of products through two methods, the gravity method and the prevacuum steam sterilization cycle.

Product Description:

The HNM EdgeHolder is made using the Kimberly Clark Kimguard sterilization wrap, which is formed into a series of pockets for the protection and origination of surgical instruments during in-house hospital sterile processing.

Test Article:**Test Article Identification:****Sample Preparation:**

Three EdgeHolders fully-loaded with instruments and a total of ten BI's each containing a population of 10^6 colony forming units (CFU), were placed into a reusable sterilization container. The fully-loaded, largest-size Duraholder represented a worst-case scenario. Ten BI's per run was selected based on TIR 13.

Methodology:

The validation was accomplished utilizing the gravity and prevacuum methods. Rigid containers were tested with both gravity and prevacuum, and EdgeHolders wrapped with KimGuard KC600 were tested with the prevacuum method. The devices were prepared with an organism that is known to be resistant to moist heat sterilization, *G. stearothermophilus*, subjected to a steam autoclave half cycle, and then tested for sterility. This was performed three times to demonstrate reproducibility.

Results:

The half cycles performed on the EdgeHolders containing the resistant organism, *G. stearothermophilus*, revealed no growth; whereas the positive control exhibited growth. The weight gain was $\leq 3\%$. No visible moisture was observed.

Conclusion:

The biological indicator results from the half cycles indicate that the recommended full cycle is capable of a theoretical 12 log reduction and will provide a Sterility Assurance Level (SAL) 10^{-6} when challenged with *G. stearothermophilus*; therefore, the study objective was achieved.



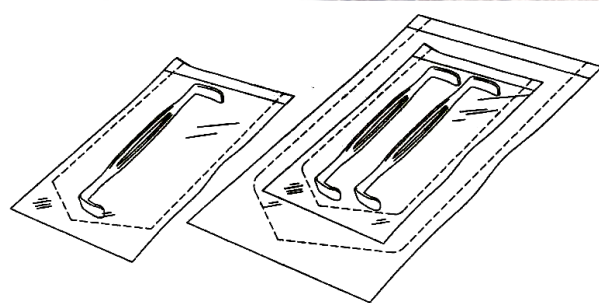
PAPER PLASTIC POUCHES

Paper -plastic pouches should be used for small, lightweight, low-profile (e.g. one or two clamps or Army- Native instruments). If the item is to be double-packaged, two sequentially sized pouches should be used (i.e. the sealed inner pouch should fit inside the other pouch without folding). The pouches should be positioned so that plastic faces plastic and paper faces paper. Paper-plastic pouches are not appropriate for use within wrapped sets or containment devices.

NOTE – Small, perforated mesh-bottom baskets with lids can be used instead of paper-plastic pouches to contain small items in sets. Small items or instruments can also be placed in an absorbent, single-layer, flat wrap or in an appropriate foam product (i.e., foam products labeled for this use) A CI should be placed inside this inner package.

Rationale: The use of paper-plastic pouches with heavy metal instruments (e.g., orthopedic drills, weighted speculums, orthodontic pliers) could result in problems with sterile maintenance, such as inadequate drying of the package after

removal, steam penetration, and drying. It is inadvisable to use paper-plastic pouches within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, steam contact, and drying. The practice of confining instruments in paper-plastic pouches and the including them in wrapped or containerized sets (Double-wrapping with dissimilar materials) has not been validated as appropriate and efficacious by any wrap, containment device, or paper-plastic pouch manufacturer.



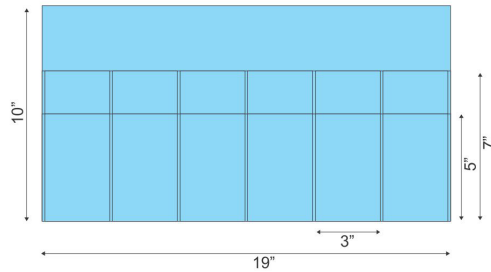
ORDERING INFORMATION



DESCRIPTION	ITEM #
Tea Spoon Metal 24 pcs/case	HNM-17506/PK
Table Spoon metal 24 pcs / case	HNM-17508/PK

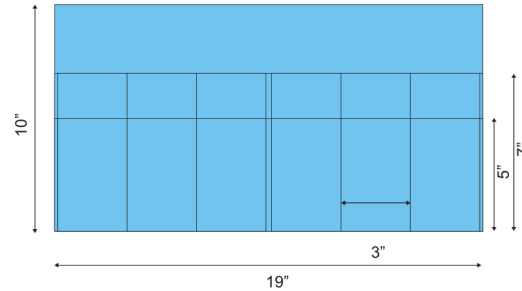
ORDERING INFORMATION

HNM-102/PK 10" x 19" 6 Pockets, 2 Rows w/Slits



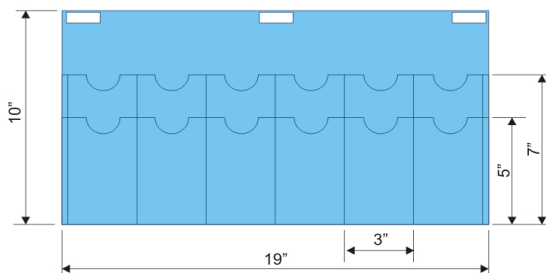
POCKETS	ITEM #
6 with slits	HNM-102/PK

HNM-602/ PK 10" x 19" 6 Pockets 2 Rows w/Slits



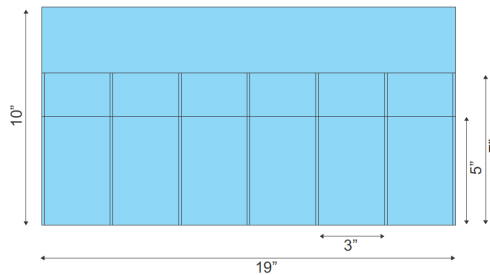
POCKETS	ITEM #
6	HNM-602/PK

HNM-200/PK 10" x 19" 6 Pockets 2 Rows w/Notches & Tape



POCKETS	ITEM #
12 pockets	HNM-200/PK

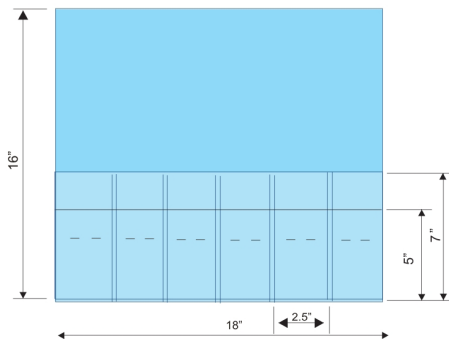
HNM-100PK 10" x 19" 6 Pockets, 2 Rows



POCKETS	ITEM #
6	HNM-100/PK

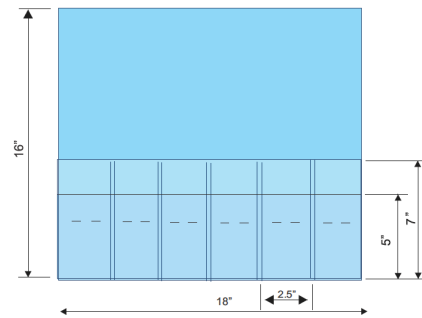
ORDERING INFORMATION

HNM-300/PK 16" x 18" 6 Pockets, 2 Rows



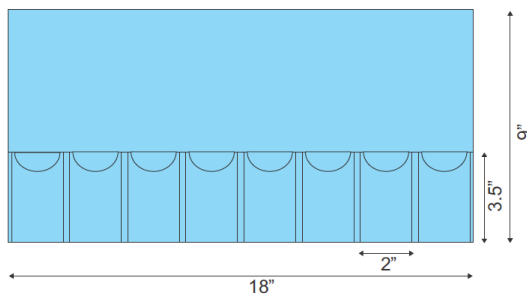
POCKETS	ITEM #
6 pockets	HNM-300/PK

HNM-602/PK 16" x 18" 6 Pockets, 2 Rows



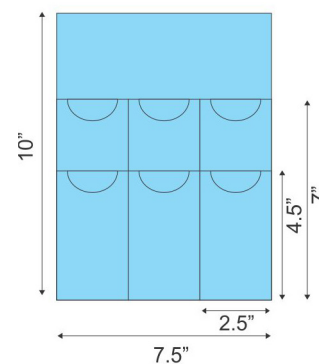
POCKETS	ITEM #
6 pockets	HNM-602/PK

HNM-009/PK 9" x 18" 8 Pockets, 2 Rows



POCKETS	ITEM #
6	HNM-009/PK

HNM-107/PK 10" x 7.5" 6 Pockets, 2 Rows



POCKETS	ITEM #
6	HNM-107/PK

