DuraHolder™ IPS

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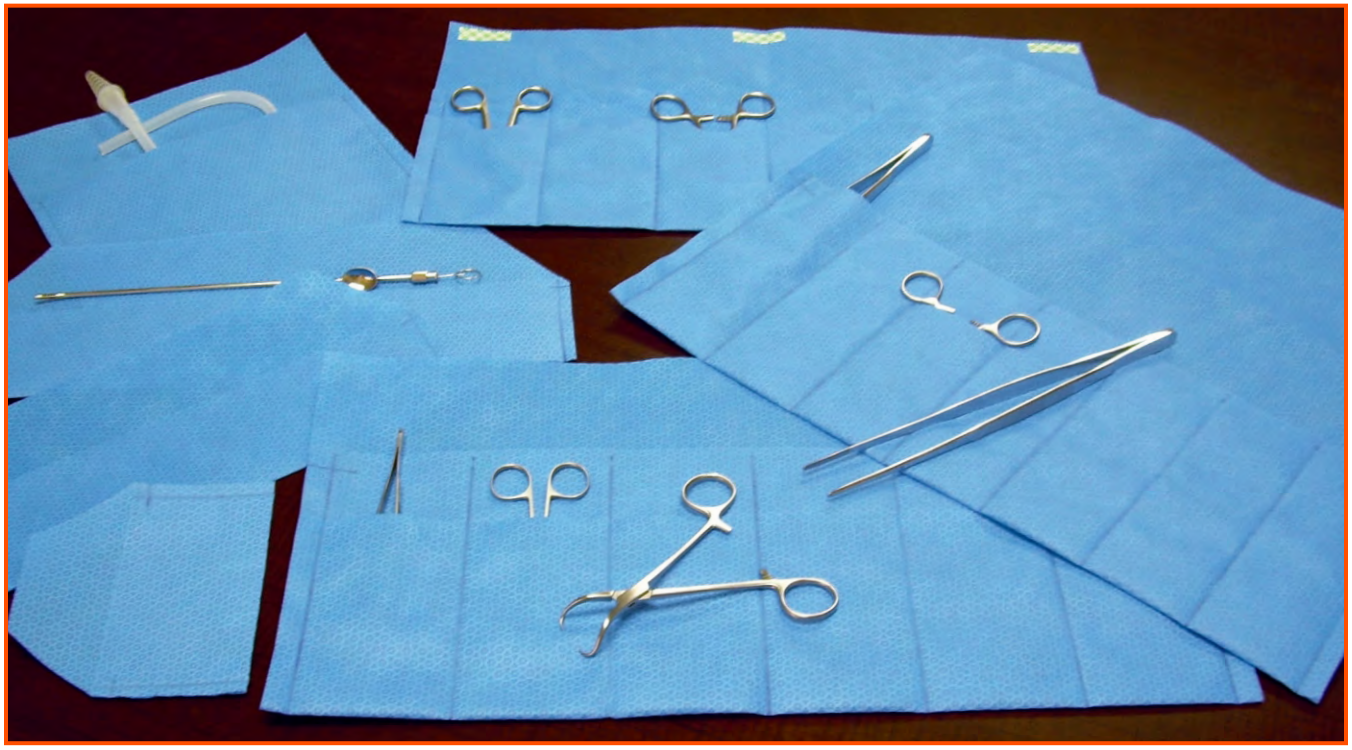
DuraHolder™ IPS



The Bioseal DuraHolder™ 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 durable Kimberly-Clark KIMGUARD* Sterilization Wrap that we use to form each DuraHolder™ IPS.

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

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

DuraHolder™ 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.

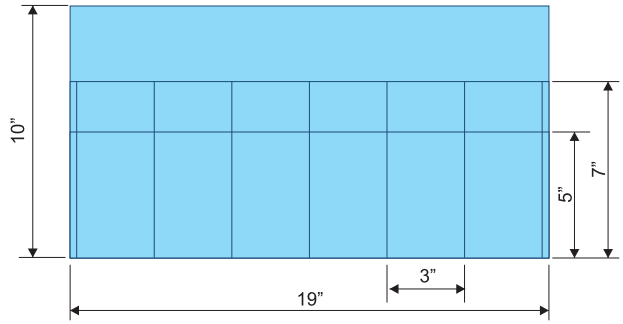
*Trademark of Kimberly-Clark Worldwide, Inc.

167 W. Orangethorpe Ave. • Placentia, CA 92870-6922 • 800.441.7325 • 714.528.4695 • Fax 714.528.8434
sales@biosealnet.com • www.biosealnet.com

DuraHolder™ IPS

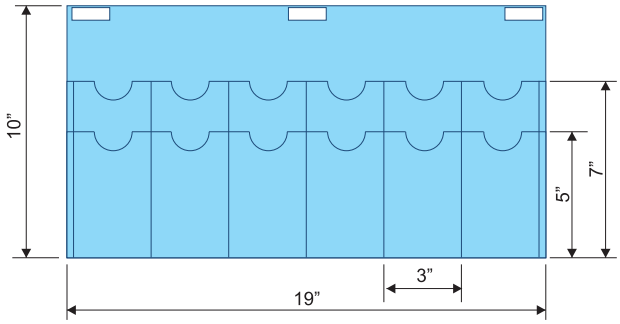
DURA100/100 *

The DuraHolder™ 100 is designed to help you protect and organize your delicate surgical instruments.



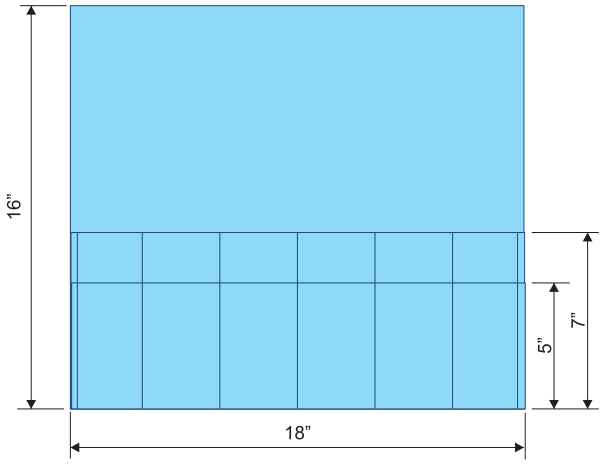
DURA200/100 *

The DuraHolder™ 200 adds the convenience of notched openings and tape closure strips.



DURA300/100 *

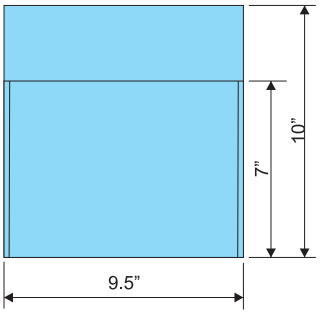
The DuraHolder™ 300 has a longer flap for added protection of long instruments.



DuraHolder™ SoloPocket IPS

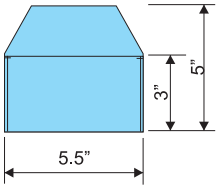
DURA050/100 *

The DuraHolder™ Solo 50 is a simple pocket with a closure flap. It comes in handy to control big floppy cables or tubing.



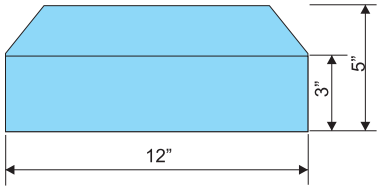
DURA505/100 *

The DuraHolder™ Solo 505 is a small pocket with a closure flap, designed to help protect the smallest parts.



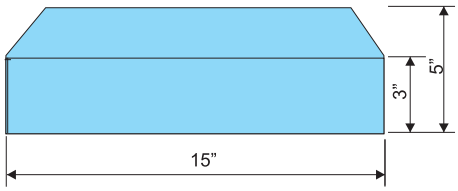
DURA512/100 *

The DuraHolder™ Solo 512 is a medium pocket with a closure.



DURA515/100 *

The DuraHolder™ Solo 515 is a long pocket with a closure.

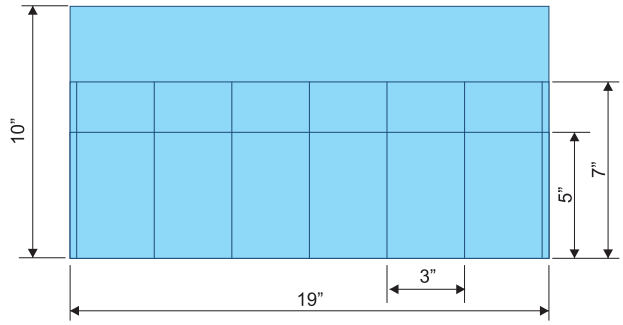


* Made with KIMGUARD* Sterilization Wrap, KC 500

DuraHolder™ lite IPS

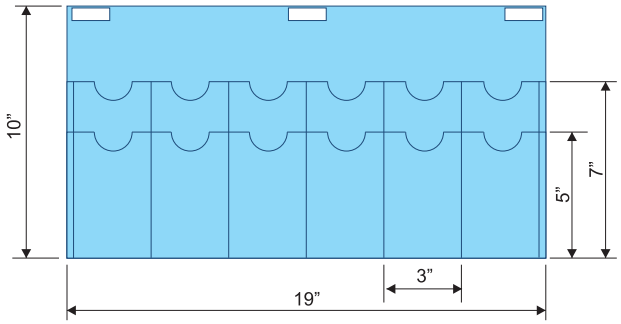
DURA710/100 ***

The DuraHolder™ 710 is designed to help you protect and organize your delicate surgical instruments.



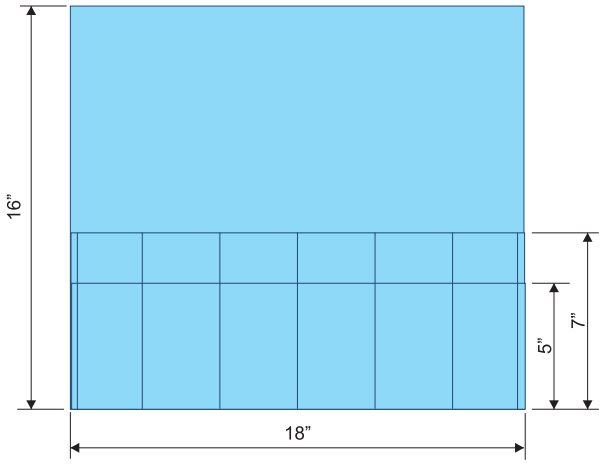
DURA720/100 ***

The DuraHolder™ 720 adds the convenience of notched openings and tape closure strips.



DURA730/100 ***

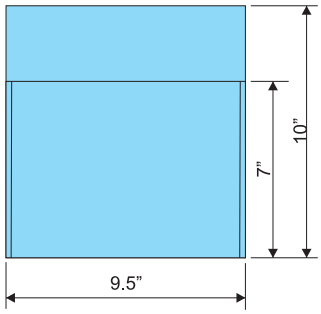
The DuraHolder™ 730 has a longer flap for added protection of long instruments.



DuraHolder™ SoloPocket lite IPS

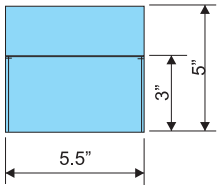
DURA705/100 ***

The DuraHolder™ Solo 705 is a simple pocket with a closure flap. It comes in handy to control big floppy cables or tubing.



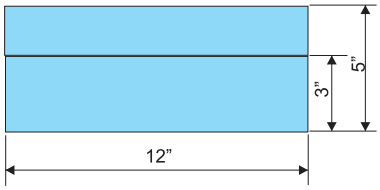
DURA750/100 ***

The DuraHolder™ Solo 750 is a small pocket with a closure flap, designed to help protect the smallest parts.



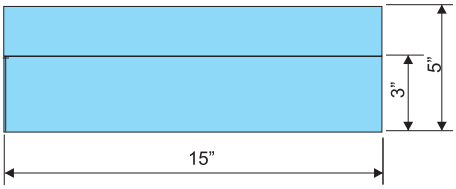
DURA752/100 ***

The DuraHolder™ Solo 752 is a medium pocket with a closure.



DURA755/100 ***

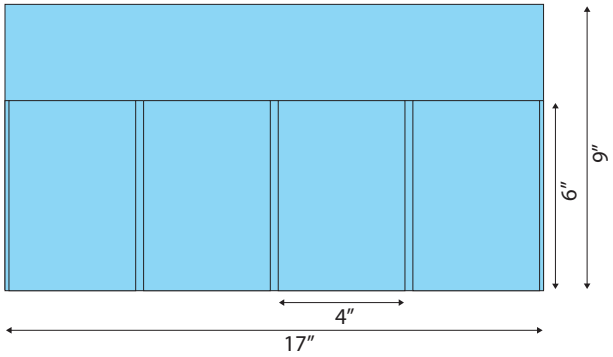
The DuraHolder™ Solo 755 is a long pocket with a closure.



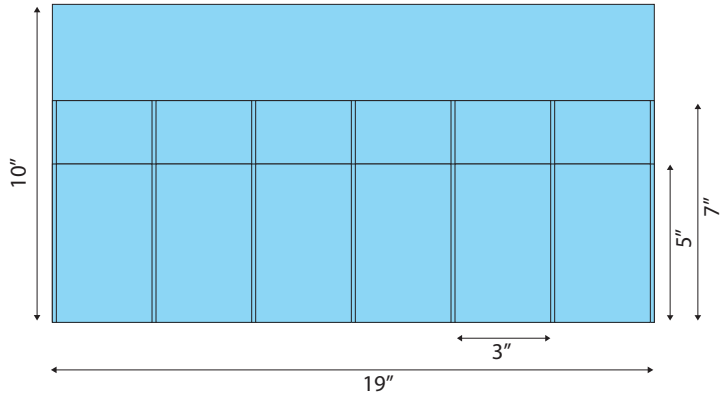
*** Made with KIMGUARD* Sterilization Wrap, KC 100, a thinner, lighter material than the original DuraHolder, making it more flexible, translucent and cost effective choice for lighter or more delicate instruments

DuraHolder™ IPS

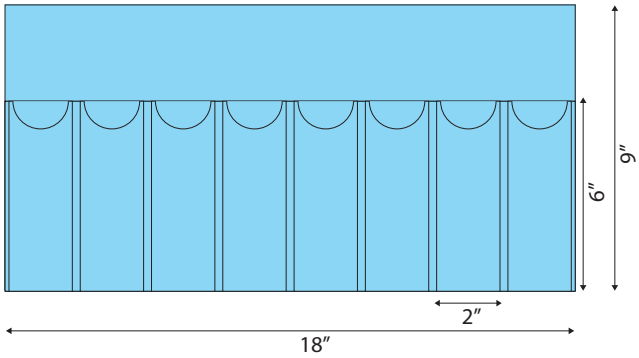
DURA004/100 *



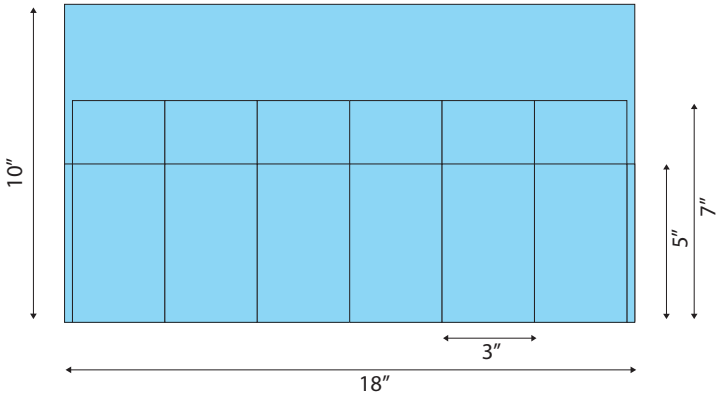
DURA100D/100 *



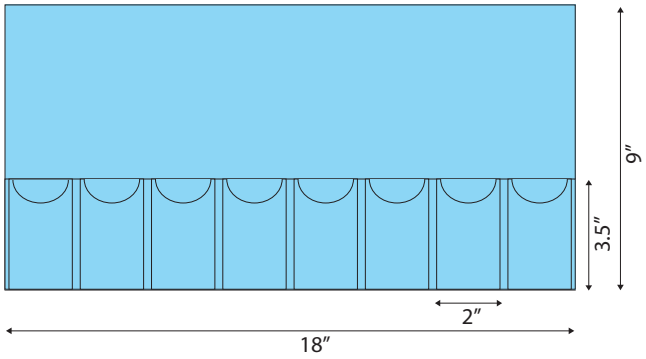
DURA008/100 *



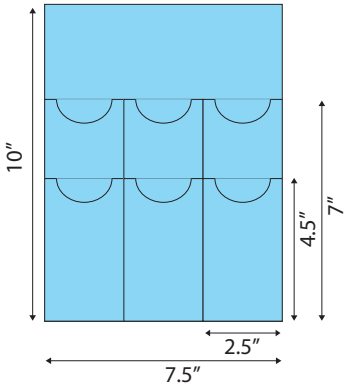
DURA101/100 *



DURA009/100 *



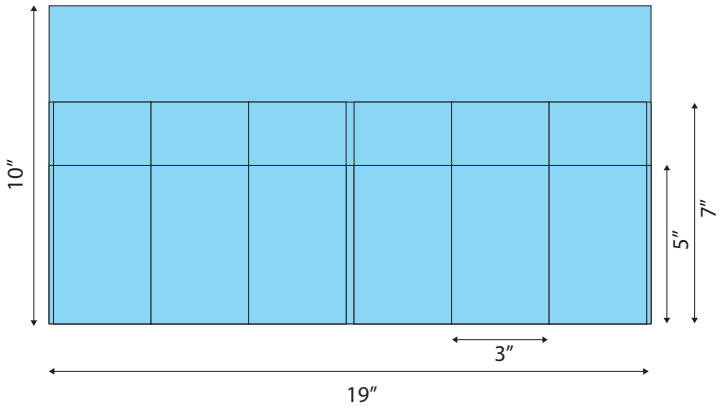
DURA107/100 *



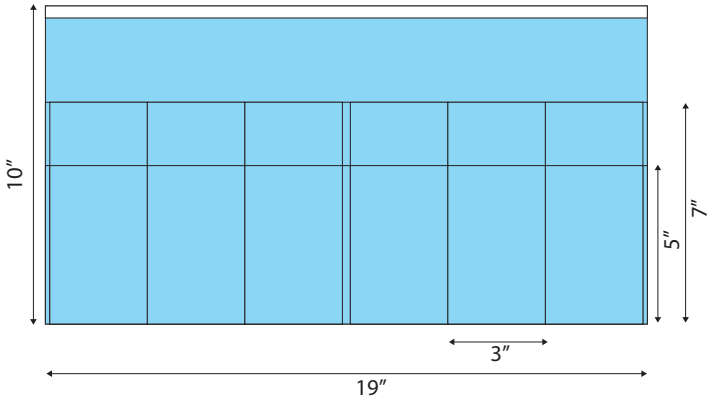
* Made with KIMGUARD* Sterilization Wrap, KC 500

DuraHolder™ IPS

DURA110/100 *



DURA111/100 *



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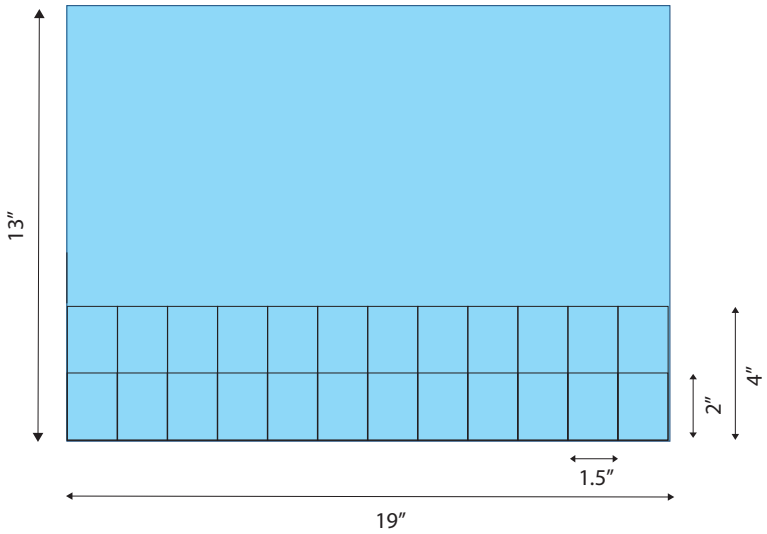
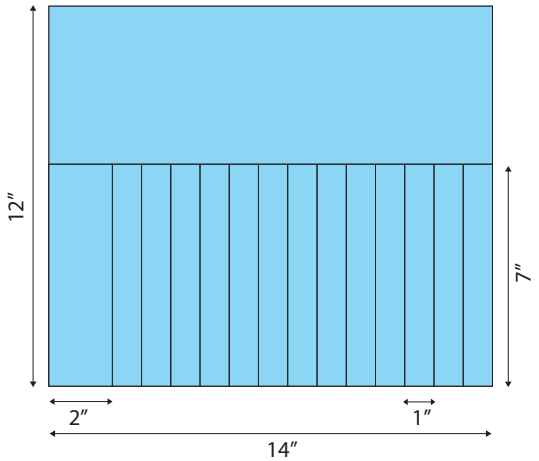


DURA114/100 *



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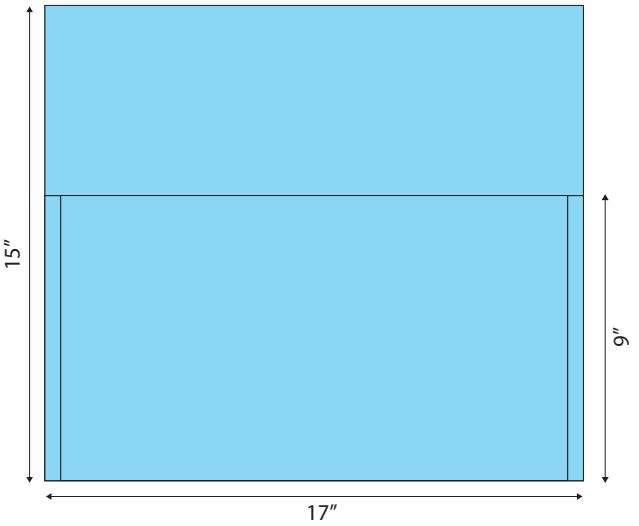
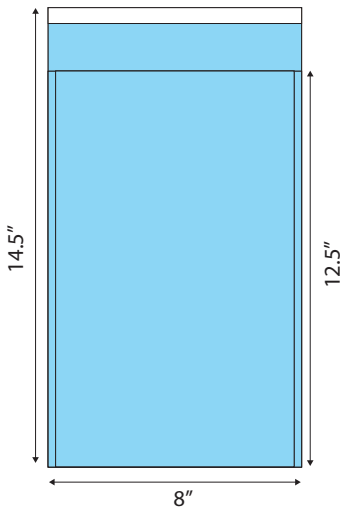
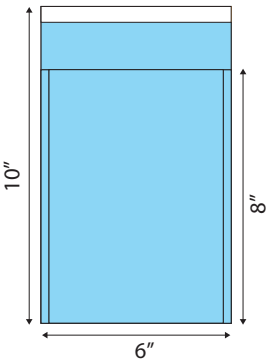


DURA118/100 *



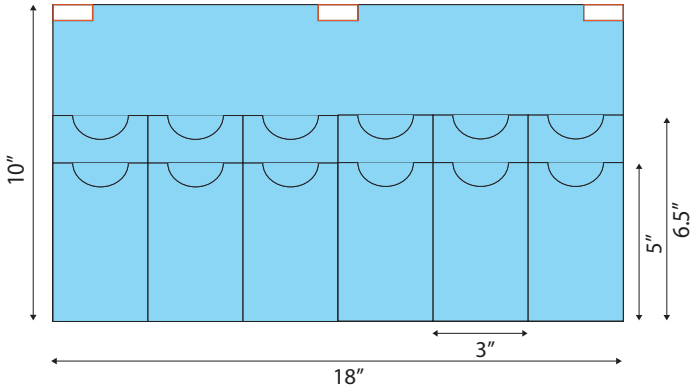
DURA116/100 *



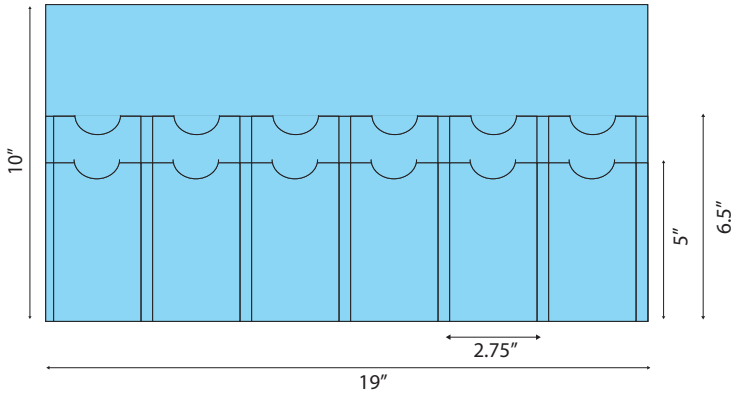
* Made with KIMGUARD* Sterilization Wrap, KC 500

DuraHolder™ IPS

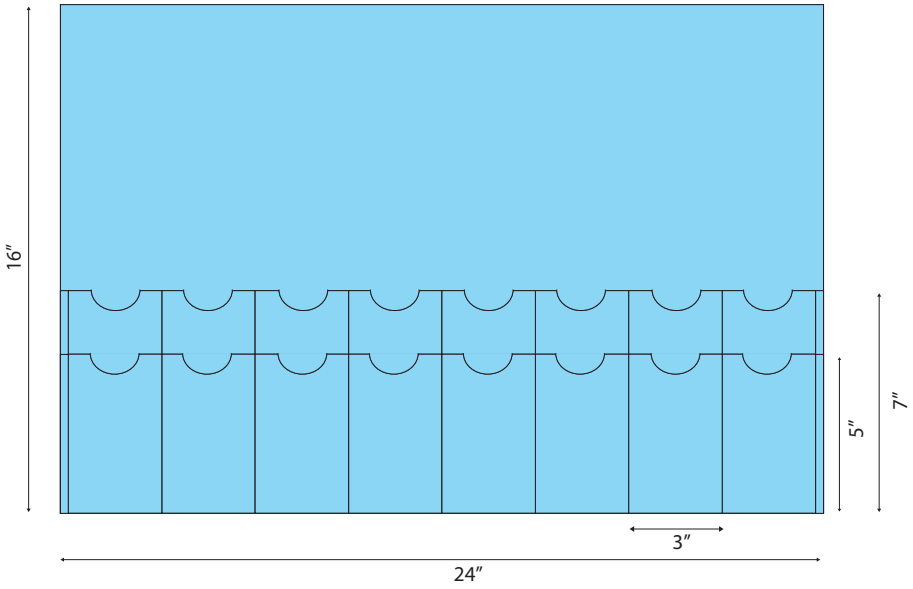
DURA200/100 *



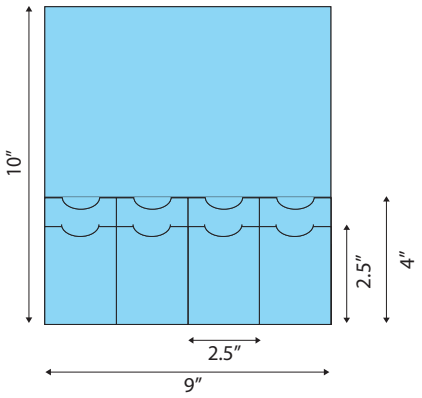
DURA202D/100 *



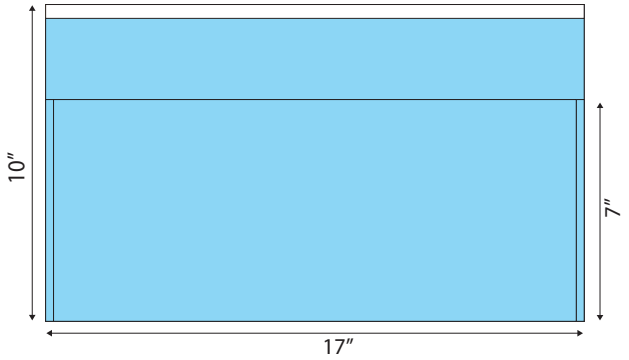
DURA202/100 *



DURA204/100 *



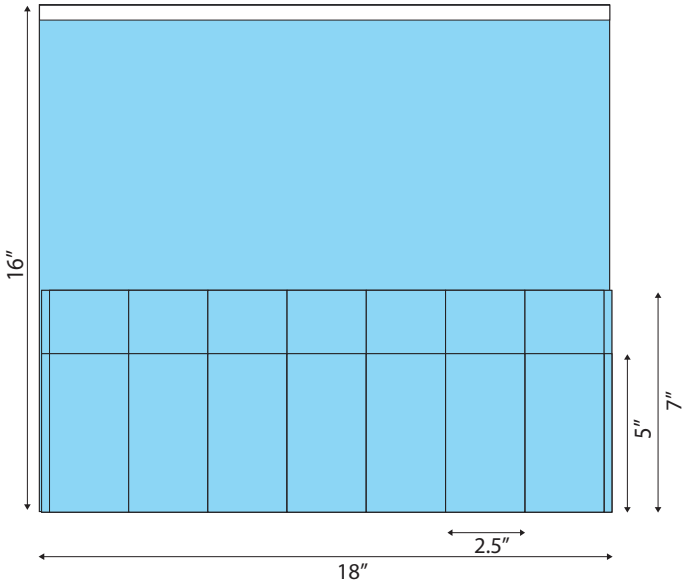
DURA225/100 *



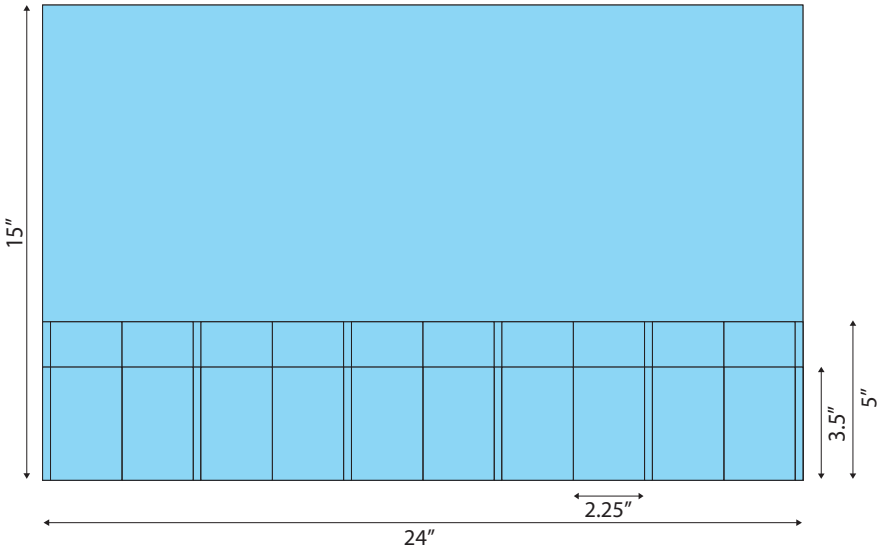
* Made with KIMGUARD* Sterilization Wrap, KC 500

DuraHolder™ IPS

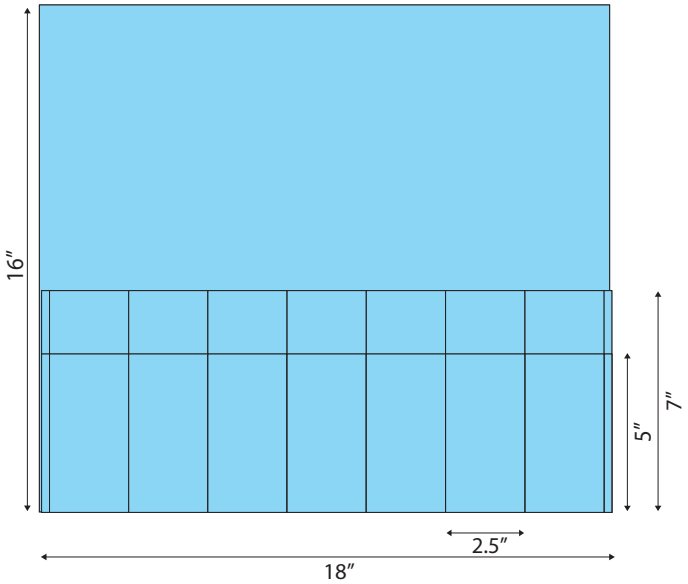
DURA300T/100 *



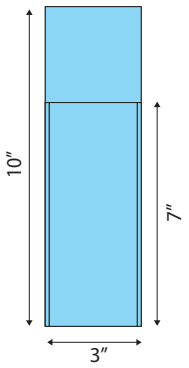
DURA303/100 **



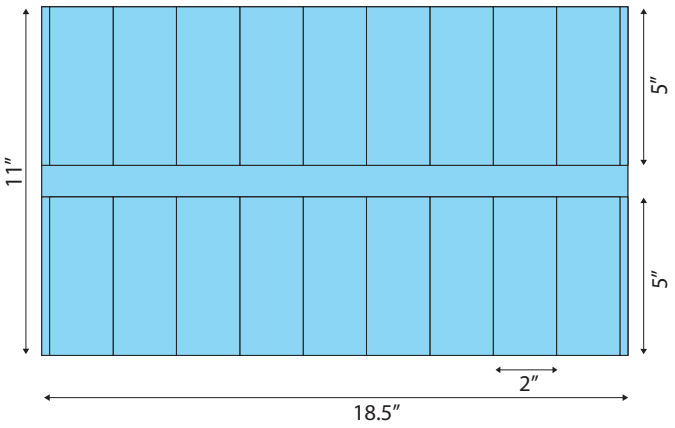
DURA301/100 *



DURA310/100 *



DURA317/100 **

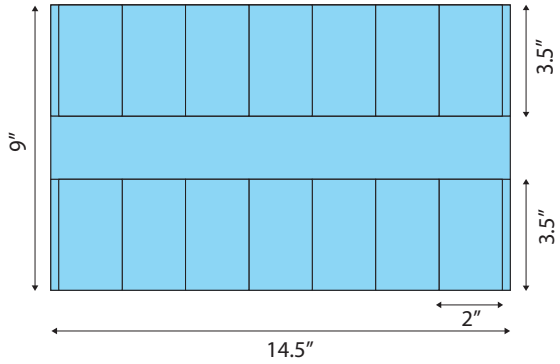


* Made with KIMGUARD* Sterilization Wrap, KC 500

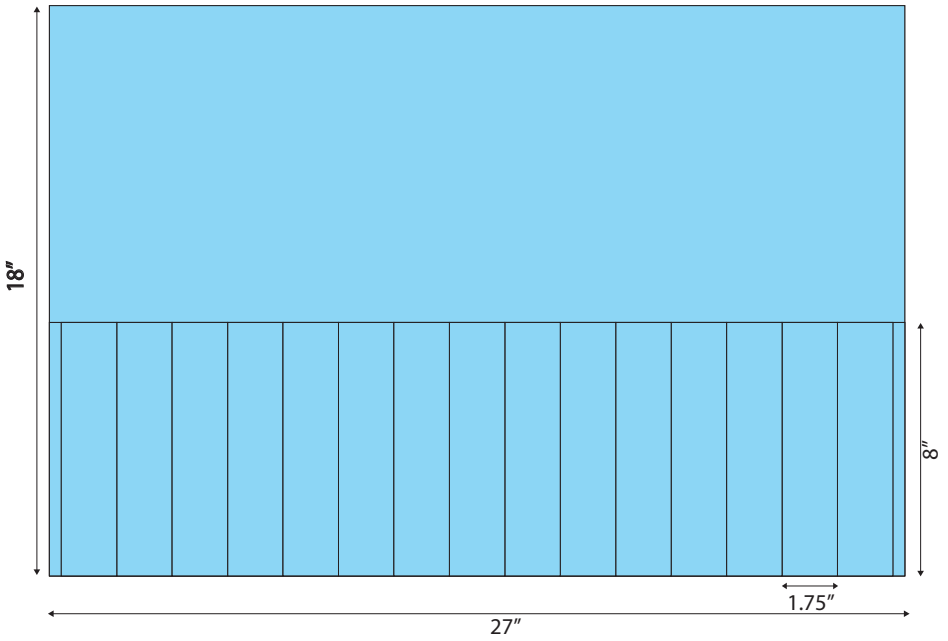
** Made with KIMGUARD* Sterilization Wrap, KC 300

DuraHolder™ IPS

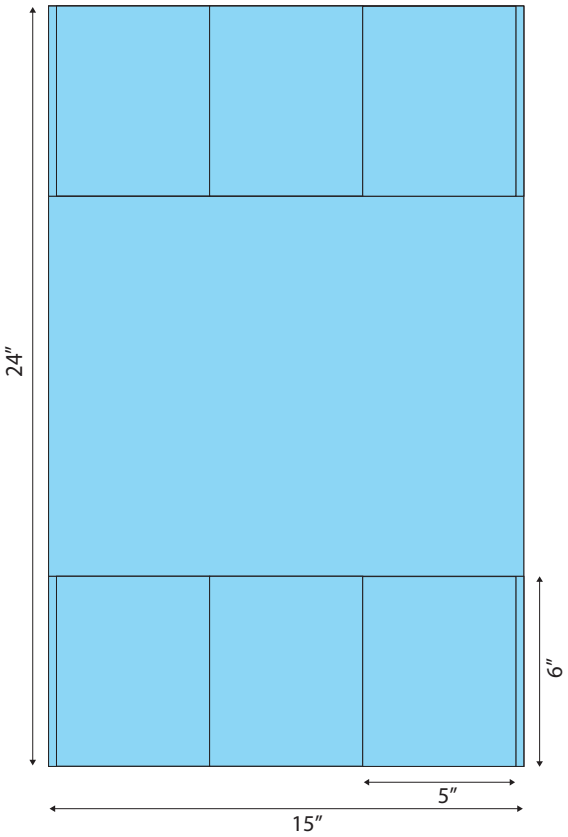
DURA318/100 **



DURA400/100 *



DURA320/100 *

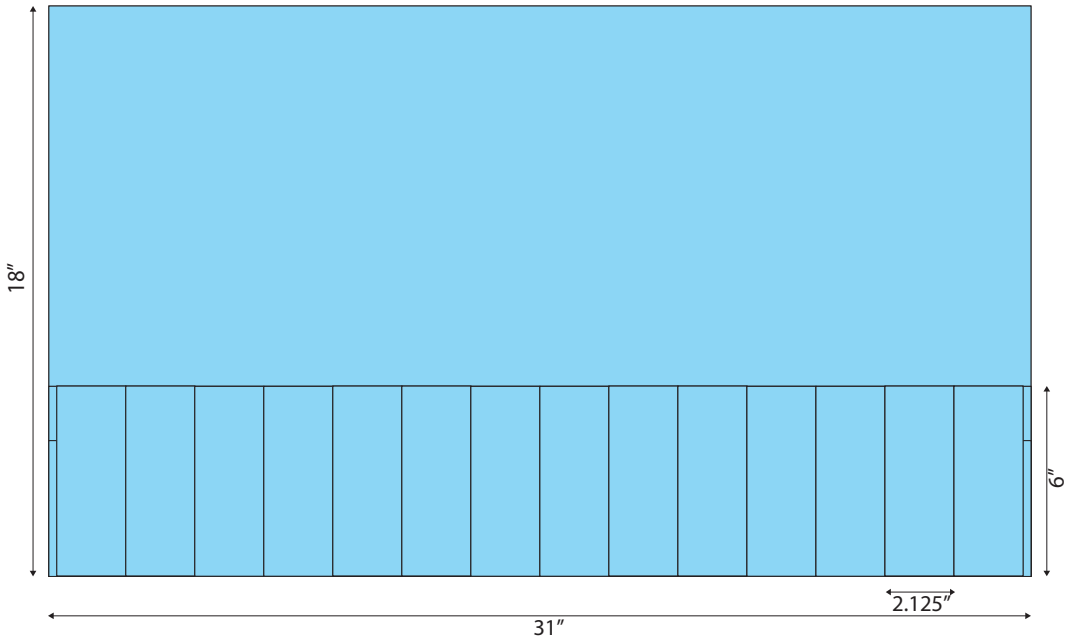


* Made with KIMGUARD* Sterilization Wrap, KC 500

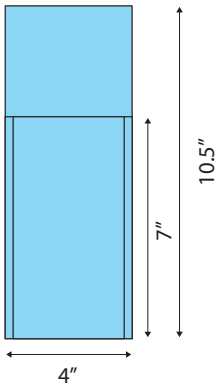
** Made with KIMGUARD* Sterilization Wrap, KC 300

DuraHolder™ IPS

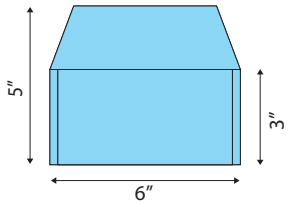
DURA401/100 *



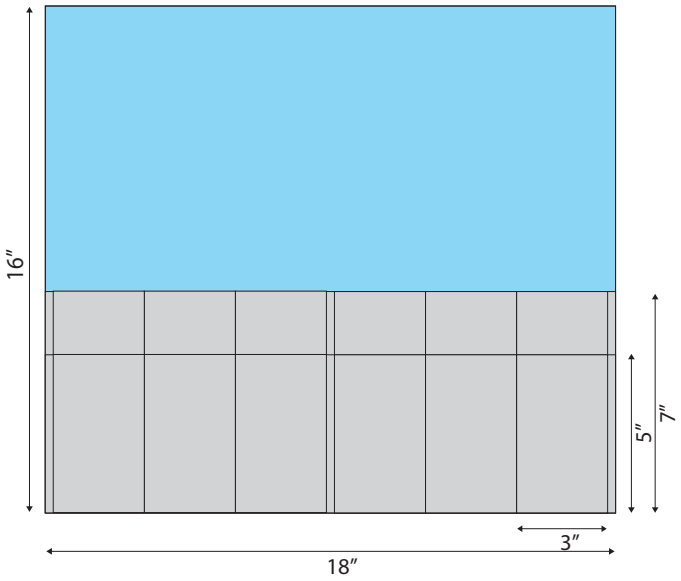
DURA415 /100 *



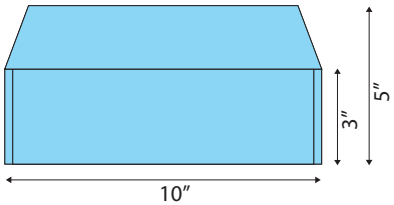
DURA506/100 *



DURA600/100 ^



DURA510/100 *

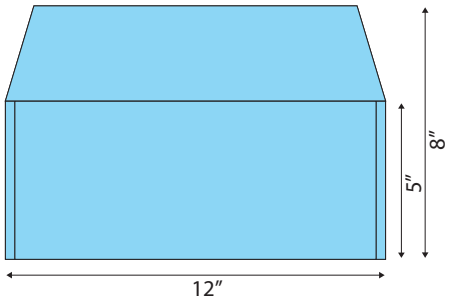


* Made with KIMGUARD* Sterilization Wrap, KC 500

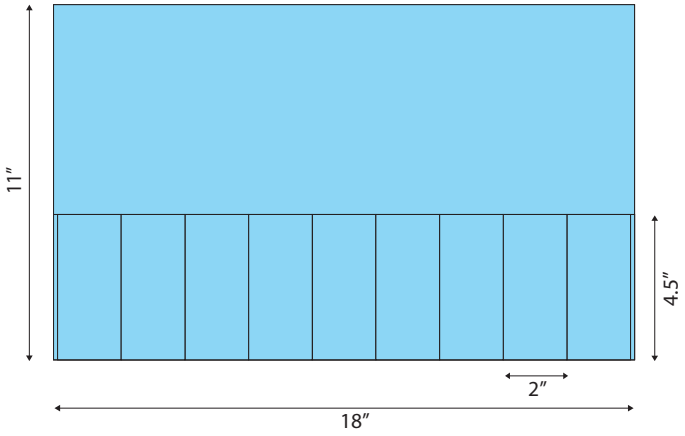
^ Made with KIMGUARD* Sterilization Wrap, KC 100 & 500

DuraHolder™ IPS

DURA812/100 *



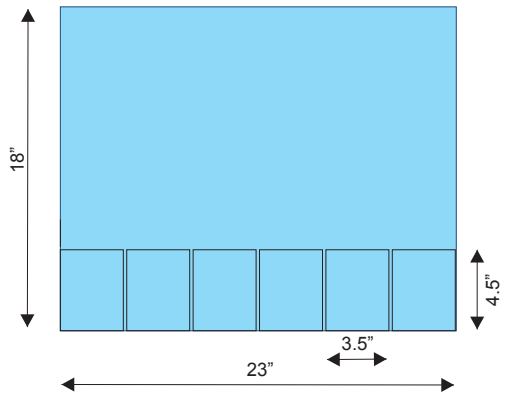
DURA1811/100 *



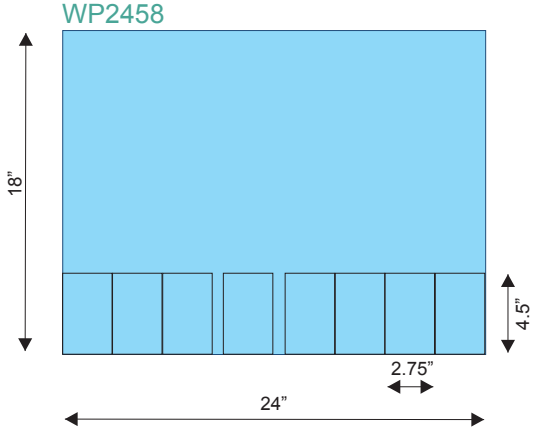
* Made with KIMGUARD* Sterilization Wrap, KC 500

DuraHolder™ IPS

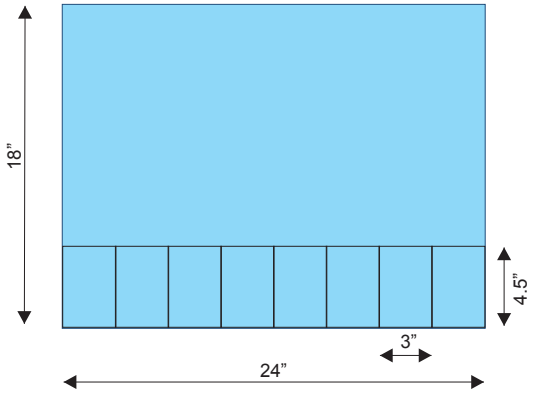
WP2006



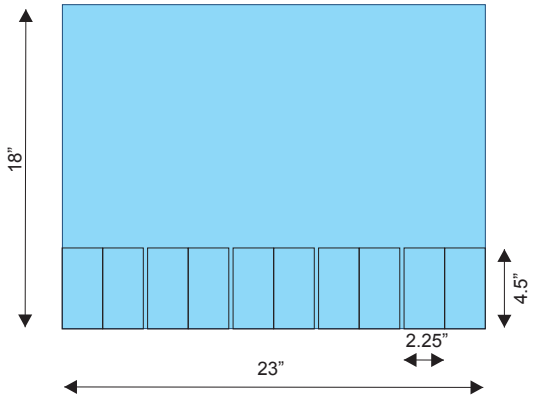
WP2458



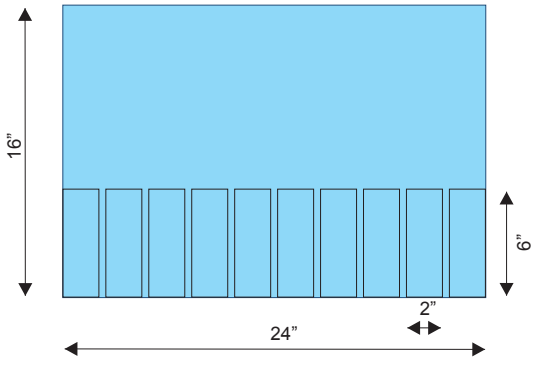
WP2008



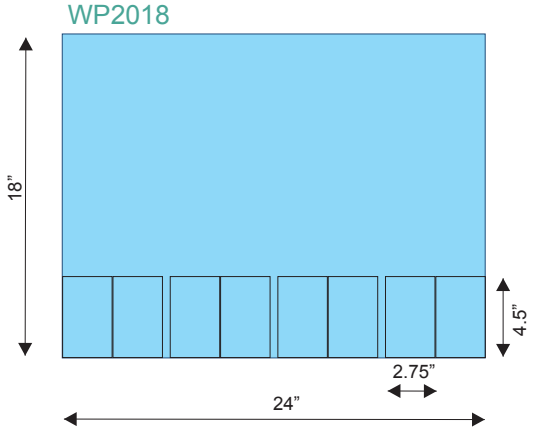
WP2010



WP2016



WP2018



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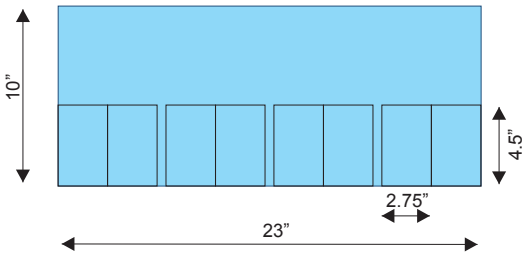
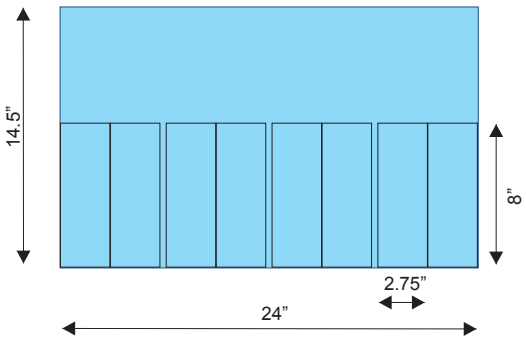
DuraHolder™ IPS

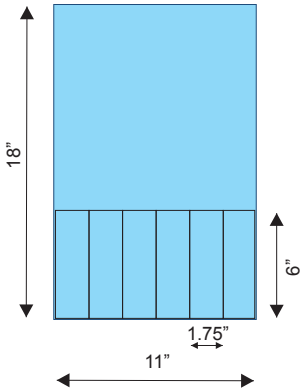
WP1018



WP2818



WP2026



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Product	Product Description	
Standard Pouches		
DURA050/100	DuraHolder 10"x9.5" 1 pocket	KC 500
DURA100/100	DuraHolder 10"x18" 6 pockets 2 rows	KC 500
DURA200/100	Mini Pouch 10"x18" 6 pockets with notches 2 rows & tape	KC 500
DURA300/100	DuraHolder 16"x18" 6 pockets 2 rows	KC 500
DURA505/100	DuraHolder 5" x 5" 1 pocket	KC 500
DURA510/100	DuraHolder 5"x10" 1 pocket	KC 500
DURA512/100	DuraHolder 5" x 12" 1 pocket	KC 500
DURA515/100	DuraHolder 5" x 15" 1 pocket	KC 500
DURA600/100	DuraHolder Hybrid 16"x18" 6 pockets 2 rows	KC 100/500
DURA705/100	DuraHolder LITE 10"x9.5" 1 pocket	KC 100
DURA710/100	DuraHolder LITE 10"x18" 6 pockets 2 rows	KC 100
DURA720/100	Mini Pouch LITE 10"x18" 6 pockets with notches 2 rows & tape	KC 100
DURA730/100	DuraHolder LITE 16"x18" 6 pockets 2 rows	KC 100
DURA750/100	DuraHolder LITE 5"x 5" 1 pocket	KC 100
DURA752/100	DuraHolder LITE 5" x 12" 1 pocket	KC 100
DURA755/100	DuraHolder LITE 5" x 15" 1 pocket	KC 100
User Designed Pouches		
DURA004/100	DuraHolder 9"x17" 4 pockets double seal	KC 500
DURA008/100	DuraHolder 9"x18" 8 pockets with notches & double seal	KC 500
DURA009/100	DuraHolder 9"x20" 8 pockets with notches & double seal	KC 500
DURA100D/100	DuraHolder 10"x19" 6 pockets 2 rows double seal	KC 500
DURA101/100	DuraHolder 10"x18" 6 pockets 2 rows	KC 500
DURA107/100	Mini Pouch 10"x7" 3 pockets with notches 2 rows	KC 500
DURA110/100	DuraHolder 10"x19" 6 pockets 2 rows double seal	KC 500
DURA111/100	DuraHolder 10"x19" 6 pockets 2 rows with tape & double seal	KC 500
DURA112/100	DuraHolder 18"x13" 12 pockets	KC 500
DURA114/100	DuraHolder 12"x14" 13 pockets	KC 500
DURA116/100	DuraHolder 10"x6" 1 pocket with tape	KC 500
DURA117/100	DuraHolder 15"x17" 1 pocket	KC 500
DURA118/100	DuraHolder 14.5"x8" 1 pocket with tape	KC 500
DURA1811/50	DuraHolder 11"x18" 9 pockets	KC 500
DURA201/100	DuraHolder 10"x18" 6 pockets with notches 2 rows	KC 500
DURA202/100	DuraHolder 16"x24" 8 pockets with notches 2 rows	KC 500
DURA203/200	DuraHolder 10"x3" 1 pocket with notches 2 rows	KC 500
DURA204/100	Mini Pouch 10"x9" 4 pockets with notches 2 rows	KC 500
DURA205/100	DuraHolder 5"x 16" with tape	KC 500
DURA210/100	DuraHolder 5"x 7.5" with tape	KC 500
DURA211/100	Mini Pouch 7 pockets 2 rows double seal	KC 300
DURA215/100	DuraHolder 11.5"x5.5" 1 pocket with tape	KC 500
DURA220/100	DuraHolder 9.5" x 19" 6 pokets 2 rows with tape	KC 500
DURA225/100	DuraHolder 10"x17" 1 pockets with tape	KC 500
DURA300T/100	DuraHolder 16"x18" 7 pockets 2 rows with tape	KC 500
DURA301/100	DuraHolder 16"x18" 7 pockets 2 rows	KC 500
DURA303/100	DuraHolder 15"x24" 10 pockets with double seal	KC 300
DURA317/100	DuraHolder 11"x18.5" 18 pockets	KC 300
DURA318/100	DuraHolder 9"x14.5" 14 pockets	KC 300
DURA320/100	DuraHolder 24"x15" 6 pockets	KC 500
DURA400/100	DuraHolder 18"x27" 15 pockets	KC 500
DURA401/100	DuraHolder 18"x 31" 14 pockets	KC 500
DURA415/100	DuraHolder 10.5"x4" 1 pocket	KC 500
DURA812/100	DuraHolder 8"x12" 1 pocket	KC 500
WP1018	Instrument Pouch 10"x24" 8 pockets double seal	KC 300
WP2006	Instrument Pouch 19.5"x24" 6 Pockets	KC 300
WP2008	Instrument Pouch 19.5"x24" 8 Pockets	KC 300
WP2010	Instrument Pouch 19.5"x24" 10 Pockets double seal	KC 300
WP2010/50	Instrument Pouch 19.5"x24" 10 Pockets double seal	KC 300
WP2016	Instrument Pouch 18"x24" 10 pockets double seal	KC 500
WP2018	Instrument Pouch 18"x24" 8 Pockets double seal	KC 300

DuraHolder™ Case Study

The Nursing and CS staff at a prominent University Hospital[1] 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.

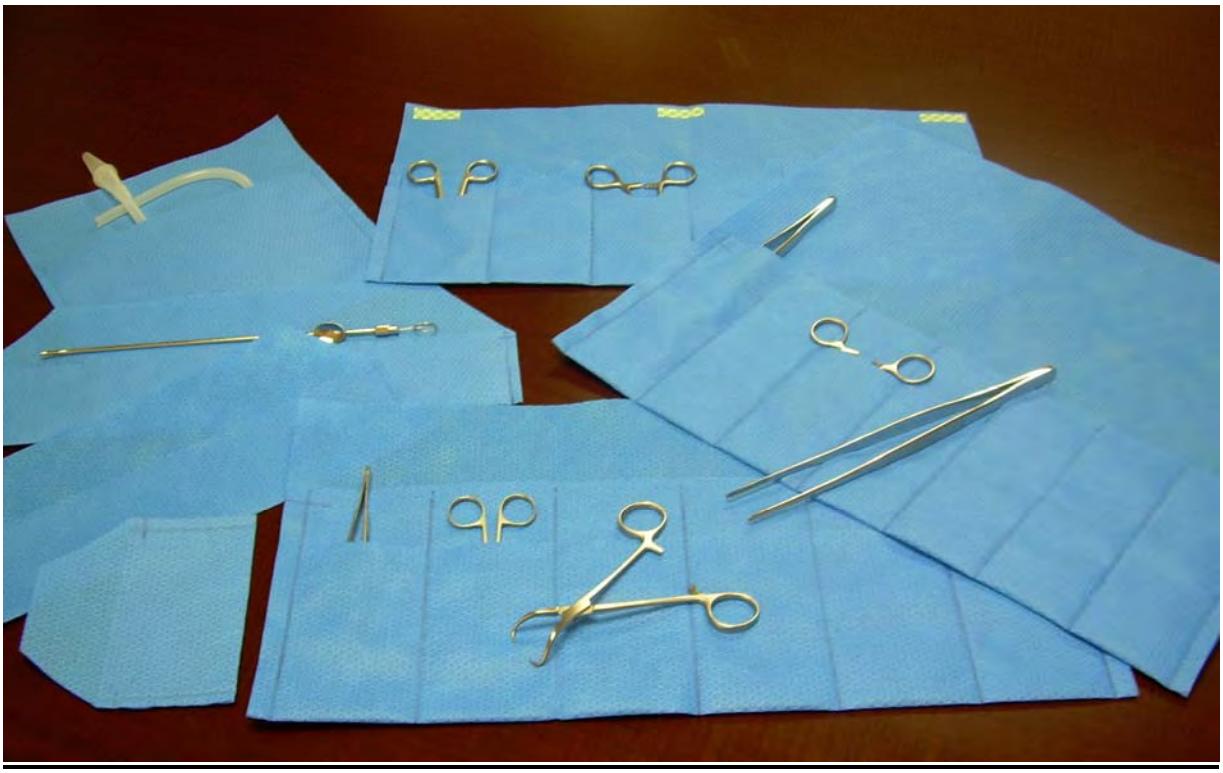
A portion of surgical instruments still pose infection risk after routine cleaning in hospitals. A 2006 study in the Journal of Hospital Infection showed that 17% of the surgical instruments tested at the point of use had unacceptable levels of residual protein and total organic matter, posing a direct infection risk.[2]

"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 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." © 2006 Association for the Advancement of Medical Instruments ANSI/AAMI ST79:2006, page 60.

DuraHolder™ Instrument Protection System

The DuraHolder™ Instrument Protection System offers a highly effective solution. DuraHolder™ is an instrument pouch made of durable KIMGUARD* Sterilization Wrap, the industry standard for sterilization wrap. This unique pouch is designed to organize and protect surgical instruments during the sterilization cycle. Instruments can be placed in the DuraHolder™ instrument pouch, then wrapped and placed directly in the steam sterilizer.

DuraHolder™ was designed for a prominent University Hospital[1] that was trying to eliminate peel packs. Once Bioseal developed the DuraHolder™, word spread quickly. Bioseal now sells the product to hospitals throughout the US. Sales continue to grow rapidly.



This photo (above) features the DuraHolder™ product with surgical instruments organized in the pouches.

DuraHolder™ helps OR nurses ensure patient safety.

- adheres to sterility and sterile product guidelines and protocols set by AAMI and ASTM and enforced by the FDA
- prevents surgery delay by improving the organization of instruments in the tray
- protects delicate instruments from damage since they are wrapped in KIMGUARD* Sterilization Wrap,

Instrument Damage is Reduced

Hospitals report that 14% of instrument set errors are from nonfunctional instruments or multi-part instruments missing components (IAHCSMM). Instrument damage can results in hundreds of thousands of dollars worth of damage each year.

Bioseal's customers have seen a decline in instrument damage after using the DuraHolder™ to organize and protect their delicate surgical instruments.

Instruments are well-organized

Instruments are better organized when they can be rolled out onto the table in the DuraHolder™. The device can even be hung from a Mayo Stand during a craniotomy.

What sets DuraHolder™ apart?
Our customers share their thoughts….

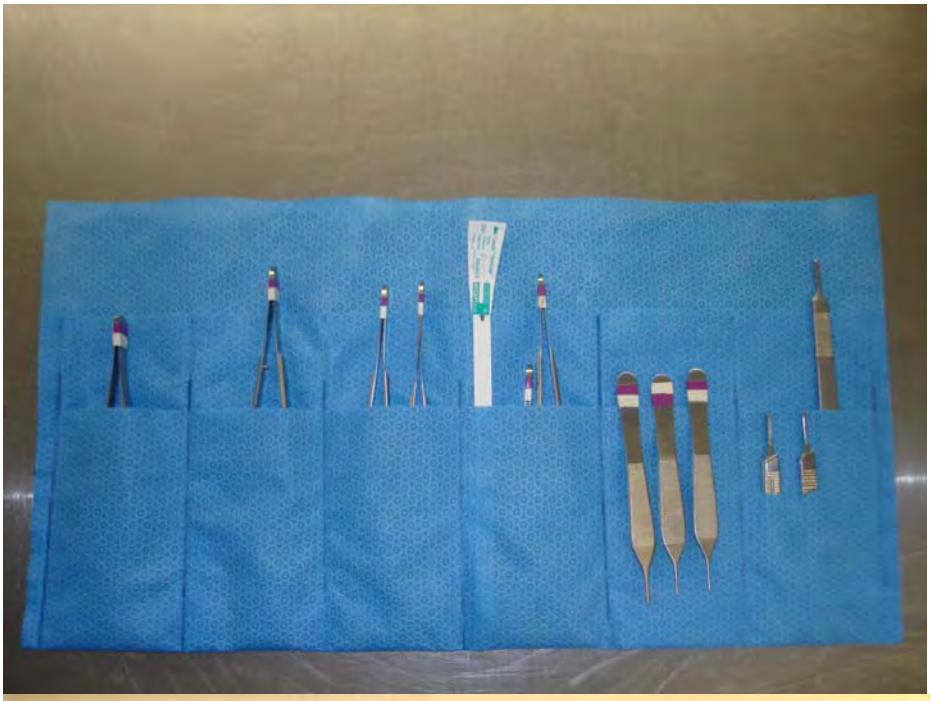
"DuraHolder ™ cannot be described in just one word because it is so versatile. It protects and organizes our specialty instruments inside the tray and on the back table. It holds instruments securely in place in the sterile field. Because this product falls within AAMI guidelines, it serves a dual role in our surgical services providing a solution in the sterilization process and convenience during the surgical procedure."
Kelly Norman, RN, CNOR, Clinical Director
Advanced Family Surgery Center
Covenant Health, Oak Ridge, Tennessee

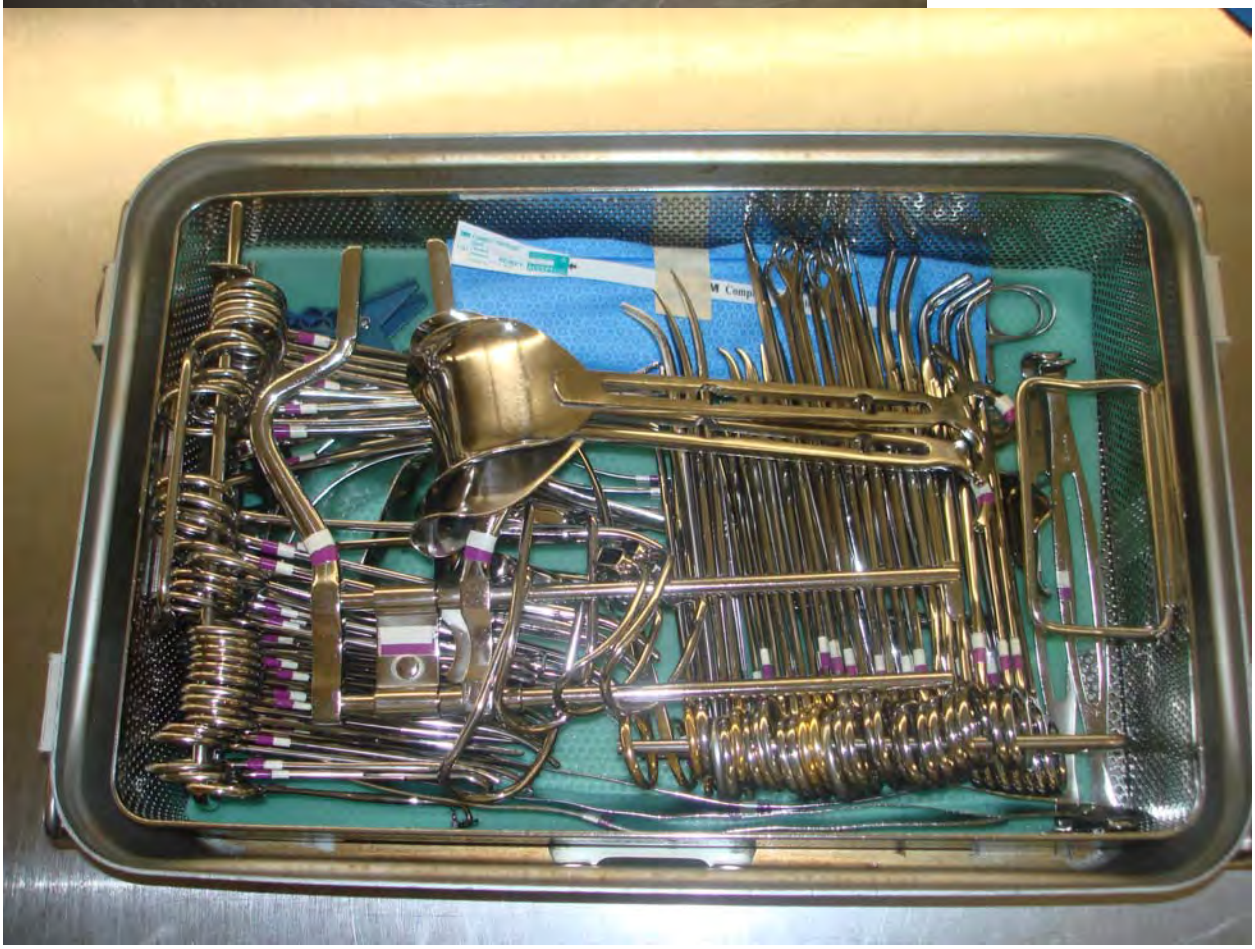
"The use of Kimguard as a sterilizing state of the art product. Plus it is a better alternative to other products on the market in terms of variety. Bioseal customized the product to fit our needs."

"When we used foam, some of the instruments would poke through the foam and fall out of the trays onto the floor. The DuraHolder™ helps us to tighten our instruments together in the right way for the Genesis trays."

The plastic instrument holder featured in this photo (below**)** cannot be wrapped and placed inside a steam sterilizer, according to AAMI guidelines. Operating room and CS staff have had to develop new solutions as a result.

This DuraHolder™ instrument pouch (below) can be filled with instruments, wrapped, placed in a tray and finally, placed directly in the steam sterilizer.





Bioseal
"Servicing Healthcare for Life"
www.biosealnet.com

About Bioseal

Bioseal delivers custom packaging and sterilization services for single-use items in the operating room and beyond.

We provide critical services to the healthcare industry, such as sterile single-use medical devices and sterile private label products. Our services range from contract packaging and sterilization services to complete product solutions for most single-use sterile medical applications.

If your product needs to be packaged, labeled and sterilized, look no further. Hospitals and medical device manufacturers have trusted Bioseal for over 18 years.

For sales assistance, please visit www.biosealnet.com or call (800) 441-7325.

Notes

1. Name withheld for legal reasons.
2. Journal of Hospital Infection, Volume 63, Issue 4, August 2006, Pages 432-438.

8.3.4 Paper–plastic pouches

Paper–plastic pouches should be used for small, lightweight, low-profile items (e.g., one or two clamps or Army-Navy instruments) (Figure 8). 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 these inner packages.

Rationale: The use of paper–plastic pouches with heavy metal instruments (e.g., orthopedic drills, weighted speculums, orthodontic pliers) could result in problems with sterility maintenance, such as inadequate drying of the package after sterilization (see 8.3.1). Proper sizing and application of pouches allows for adequate air 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 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.

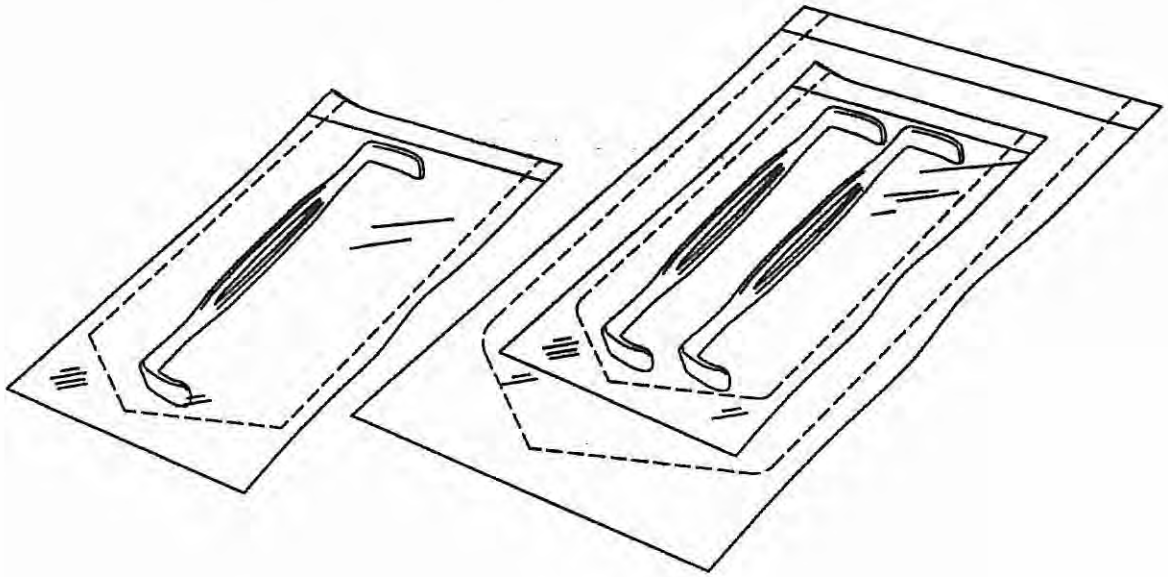


Figure 8—Example of single- and double-packaging with paper–plastic pouches

NOTE—Instruments should be oriented within paper–plastic pouches according to the health care facility's policies and procedures.

Steam Sterilization Efficacy Testing using Bioseal® DuraHolder™ Instrument Protection System (IPS)

Objective:
The objective of this study was to qualify the Bioseal® DuraHolder™ Instrument Protection System (IPS) family of products in a steam sterilization cycle.

Product Description:
The Bioseal DuraHolder 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:

Name:	Bioseal® DuraHolder™ Instrument Protection System (IPS)
Product Number:	DURA300/100. The DURA300/100 is the largest DuraHolder device in the product family. It was chosen to represent the product family based on its largest size and number of pockets.
Physical State:	Device – non-sterile

Control Article:

Name:	*Geobacillus stearothermophilus*
Physical State:	Spore strips – *G. stearothermophilius* was chosen to serve as the microbial challenge based on its resistance to moist heat sterilization.
Population:	1.6×10^6 per strip

Sample Preparation:
Eight DuraHolders 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 overkill method. The devices were prepared with an organism that is known to be resistant to moist heat sterilization, *G. stearothermophilius*, 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 DuraHolders containing the resistant organism, *G. stearothermophilius*, revealed no growth; where as, the positive control exhibited growth.

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.

References:

ANSI/AAMI/ISO 11134-1993	*Sterilization of Health Care Products – Requirements for Validation and Routine Control – Industrial Moist Heat Sterilization.*
AAMI TIR No. 12-2004	*Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufactures.*
TIR 13	*Principals of Industrial Moist Heat Sterilization of Medical Products – AMMI Technical Report.*

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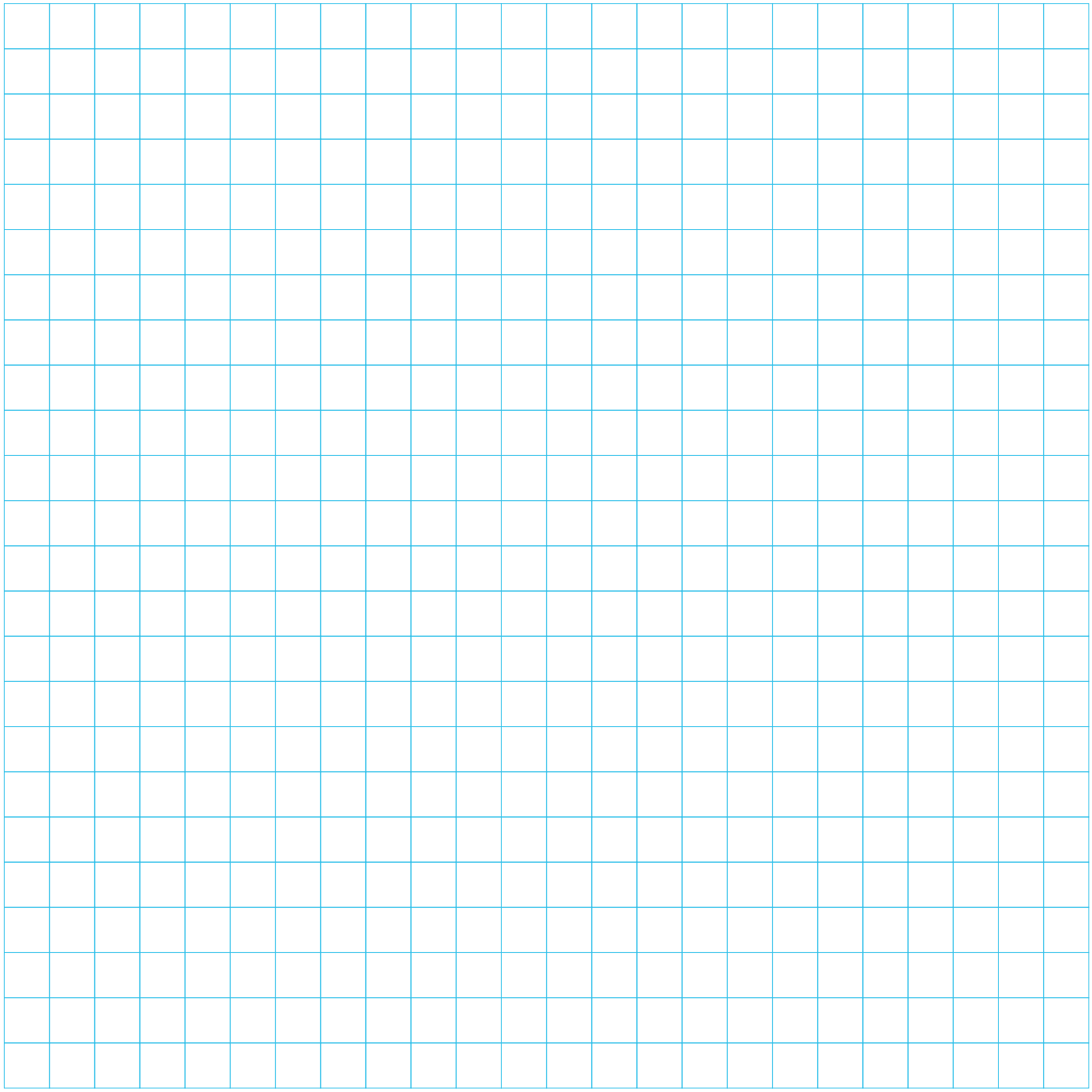
Design Your Own!



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