

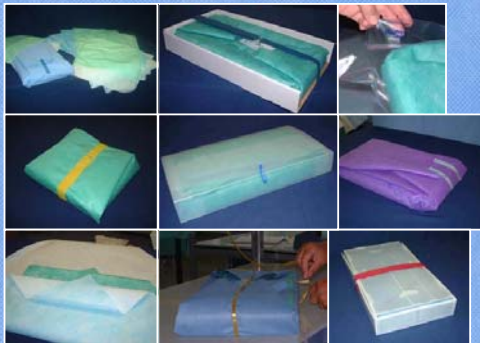


A short study of sterilisation packaging materials and final pack integrity.



Sterilisation Packaging Materials

There are many different types of products available today for packing small and large packs and many different methods of packaging. This short study, attempts to clarify the differences of these products and how they may be used to best advantage.



Sterilisation Packaging Materials

This study limits itself to products used for packaging for steam sterilisation which is still the most commonly used form of sterilisation in hospitals today.

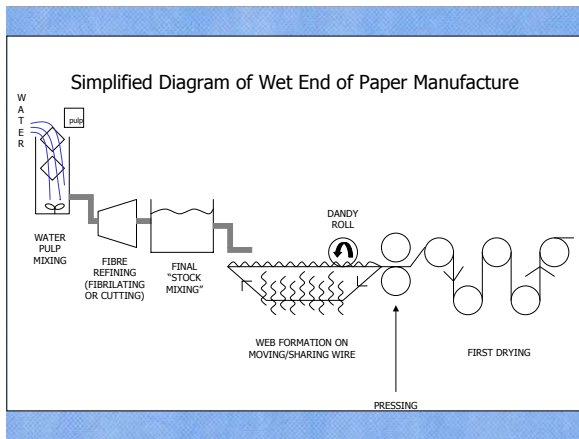
Woven Linen Structure



Linen was mostly used for wrapping theatre trays over 50 years ago, and this material is very compatible to the autoclaving process, as it allows air removal and steam injection easily and helps spread condensate, because it is absorbent. The woven structure of linen however, meant that it could not be considered at that time as a bacterial barrier, it is also prone to linting and requires washing and checking and repairing when necessary.

Paper was first used for the production of bags into which small dressings and dressing trays could be packed and autoclaved.

This was the beginning of the single layer bacterial barrier sterilisation materials, which we will call here **Single Layer cellulose/synthetic wraps**.

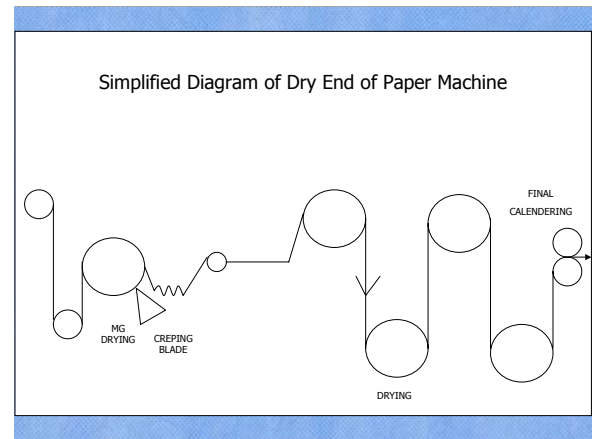


These products are made on a paper machine which we try to illustrate diagrammatically here.

Water and wood pulp are put into a large mixing tank and the cellulose fibres are put into suspension in water.

From here that are pumped to a refining process which fibrillates and modifies the fibre to enable the ends to intertwine.

It is then pumped to a headbox where final dilution occurs and it is forced onto a moving wire which also shakes from side to side, thus mixing the fibres together, while the water drains away. The dandy roll compresses the surface and the 'sheet of paper', still very wet, is lifted away into the first press and then over the bank of drying cylinders. So you can see that everything is made in one layer and the quality of the product much depends on the cellulose used, the processing of that cellulose and to some extent the quality of the water.



The sheet will then move to the dry end of the machine, the first part of which may well be a large MG cylinder. The web passes over this and if required dried very quickly. This is often done in the case of sterilisation bag paper.

However it may also be run very cool and wet creping carried out, by this creping blade. (Creping can also be carried out on cylinders at the wet end, but the principal remains the same).

Crepe Paper

The image shows a technical specification sheet for crepe paper. A red box highlights the 'Physical Properties' section, which lists various mechanical and physical characteristics.

Elongation	>10%
(cross direction)	>2%
Water Repellency	>20 sec
Max Pore Size Diameter	<50um
Drape	<125mm
(cross direction)	<160mm
Tensile Strength	>1.33kN/m
(cross direction)	>0.67kN/m
Wet Tensile Strength	>0.33 kN/m
(cross direction)	>0.27 kN/m

So this is how **Bag Papers and Crepe Papers are made**. Of course the quality of wood pulp, the porosity strength and other factors are all regulated so as to conform to EN 868 part 1 which we copy here.

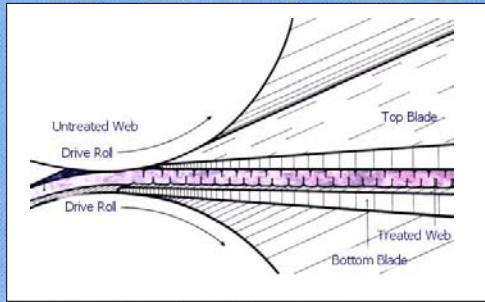
It is important to remember that the barrier resistance of these products relies heavily on the work done on the fibres which must still allow air and steam penetration but still prevent the ingress of bacteria.



Sometimes additional softening is done on an off machine dry creper and these processes vary greatly. The most common used being the Micrex process.

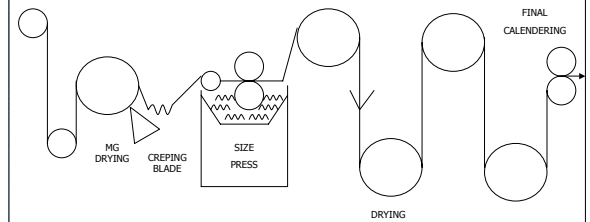
These processes can weaken the crepe slightly but for medical packaging purposes can greatly benefit the product by imparting greater softness and stretch. These products are usually known as **Softened Crepe**.

Micrexer diagram



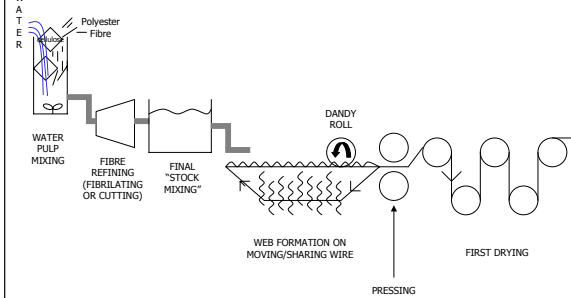
Micrexer

Simplified Diagram of Dry End of Paper Machine



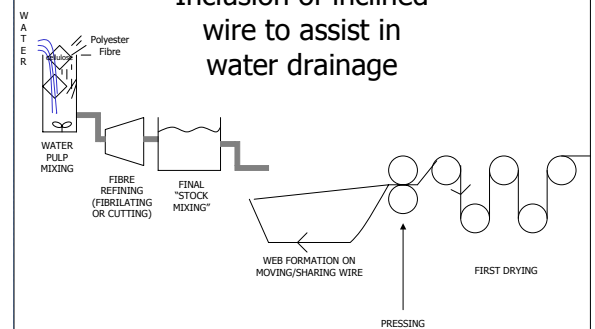
The last of the cellulose products are the reinforced crepes, which are produced in a very similar manner to the normal crepe papers, but after the creping process, are put through a bath containing acrylic binders. This bath often contains the colouring as well as the binders and up to 16 grams of binder can be impregnated. The strength and water resistance is provided by these binders and the amount of physical adjustment at the refining end is greatly reduced. These **Reinforced crepes** fall under the same EN868 specifications as crepe and softened crepe and are still widely used in many countries and were an early competitor to the first **Wet laid non wovens** which we come to next.

Wet Laid Non Wovens



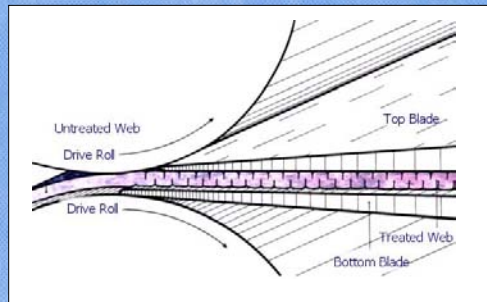
Wet Laid non Wovens (often referred to in our trade as Non Woven Wraps) are made on similar machines as sterilisation paper and crepe papers but, in the early stages of manufacture polyester fibres are added to the crepe water mixture. Obviously these polyester fibres are treated to assist spreading and mixing. The fibres are very long (in comparison to cellulose fibres) and provide softness and strength. Very little refining is carried out to avoid damage to the synthetic fibres.

Inclusion of inclined wire to assist in water drainage

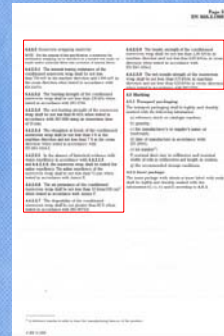


Sometimes an inclined wire is used to assist in water drainage and help achieve better formation and faster running speeds, and then the process may be similar to that used for reinforced crepes, where acrylic binders may be added to give excellent strength water repellence etc. In addition special treatments may be carried out to achieve alcohol repellence. Otherwise the process is very similar to the production of softened crepe with a final treatment through a dry softening process.

Micrexer diagram



Wet Laid Nonwoven Material



Internal tear resistance	> 750mN
(cross direction)	> 1000mN
Bursting Strength	>130kPa
Wet Burst Strength	>90kPa
Elongation	>5%
(cross direction)	>7%
Saline repellency	>75min
Air permeance	>10 l/min/100cm ²
Drapeability	<85%
Tensile Strength	>1.00kN/m
(cross direction)	>0.65kN/m
Wet Tensile Strength	>0.75 kN/m
(cross direction)	>0.5 kN/m

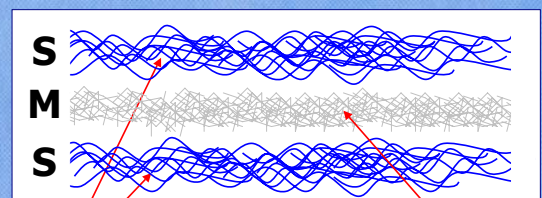
These Wet laid non wovens have a separate specification within the En standards as shown here and represented the leading edge of wet laid technology when the standards were introduced.

This, very simplified explanation of basic bag papers, crepe papers, softened crepe papers, reinforced crepe paper, and finally wet laid non wovens will I hope serve to help you understand the construction of these single layer products. It is important to understand these so that you may understand how other products have developed using entirely different processes, with the same objective, of providing you with a greater choice of Sterilisation Wraps.



The next type of Sterilisation wraps we will look at, are those only produced from synthetic fibres. These are probably recognised by you under the description of SMS products. SMS stands for Spun – melt – Spun and refers to the spun polypropylene used on the outer layers and the melt polypropylene used in the middle.

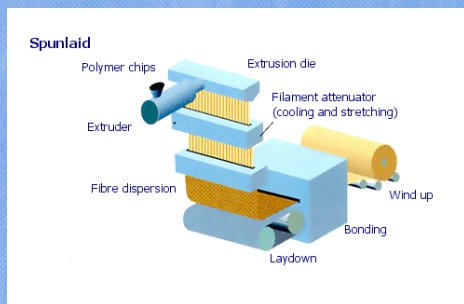
SMS Wraps



This simple diagram illustrates this type of construction, where you can see the long and strong outer fibres which provide the strength and the very fine and short melt fibres, providing the filtration layer.

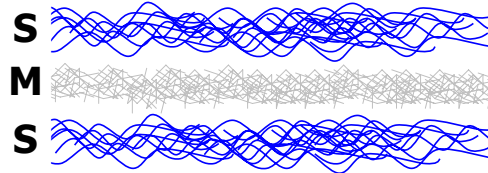
A short study of the processes may help you understand how these products are so different to those manufactured under the single layer process already described.

Spunbonded Process

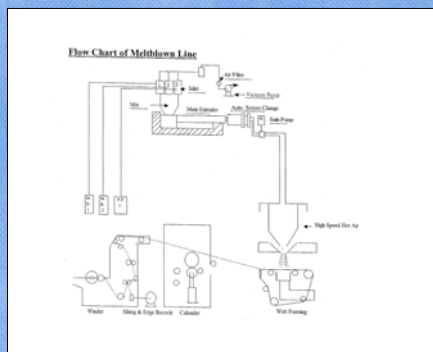


In the spunbonded process the polymer granules are melted and the molten polymer is extruded through spinnerets. This produces continuous filaments which are cooled and stretched and then forced onto a web forming process. Therefore you can see that the fibres are continuous and are generally quite large in diameter. Thus providing considerable strength. Obviously there are differences from manufacturer to manufacturer and some will have thicker fibres. Also some machines may provide additional fibre to fibre bonding by melt product and the strength. So this product is used as the outer layer for the SMS products.

SMS Wraps

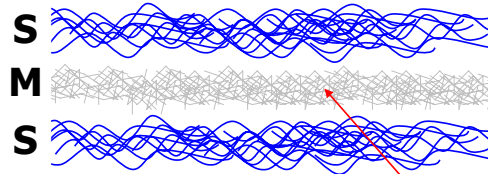


Flow Chart of Meltblown Line



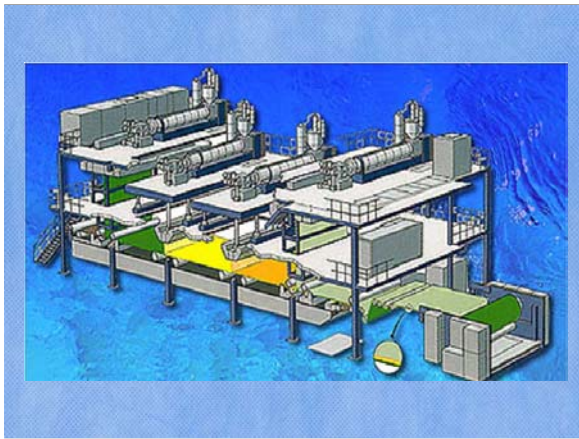
For the inner layer melt blown fibres are used. This is a different process producing very fine, discontinuous fibres, which when made into a sheet have no strength. On the other hand this product provides an excellent filtration layer and when bonded together with a spun bonded product, the properties of strength and filtration are combined. The melt blown process is expensive in comparison to the spun bond process, and the faster the machines run, generally speaking, the diameter of the fibres increase making the filtration properties diminish. The weight of this layer is also important and the higher the weight, the slower the machine speed.

SMS Wraps



Filtration

Because the melt blown layer has no strength and the fibres are so short, it is usual for this layer to be bonded into the middle of the sheet, so that you have two layers of Spun bonded material, on the outside, fully enclosing a filter layer of melt blown fibres in the middle, hence the term SMS.



Mostly, but not always, these products can easily conform to the minimum standards described in EN868, for Non woven materials and have the advantage of being very soft and comfortable.

There are variations to this combination and more recently SMMS machines have been developed which run at high speeds and produce all the layers continuously in one long line.

First the spun layer is produced and then a layer of melt followed by another. Usually these layers are of a light weight, to facilitate the highest possible running speeds and also, because of the high speeds, the fibre diameter may be quite large. Finally a layer of Spun is produced thus producing in one manufacturing process as SMMS.

The temptation with these products is to take the fact that there are two layers of melt blown material in these products, that the result is a filtration layer twice as good as that produced in SMS materials, but this may not always be the case!!

Finally Clinipak was well aware that the more synthetic products used in the wrapping materials used for steam sterilisation, the greater tendency there is, for the wetness problems. We have traditionally helped to overcome this problem, by the use of absorbent liners with the principal that the condensate is spread over a wide area allowing a greater surface area exposed to the warming effect on the trays and autoclave shelves.

SMA Wraps



We therefore developed our own wraps utilising the spun and melt layers, to give us strength and filtration and the third layer made to be absorbent with natural materials. This we call SMA and this product has been enormously successful in providing the properties of the SMS products while achieving dry processing similar to that you would have expected when just using linen. Again this conforms easily to the EN868 standards.

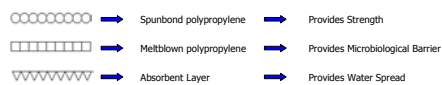
Choice Dry – 'New concept' Sterilisation Wrap



Concept

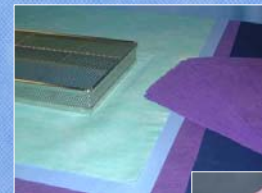
- A revolutionary sterilisation wrap complying with the essential requirements of a conventional non-woven wrap being a microbiological barrier both wet and dry and yet being permeable to steam and gas but with one surface absorbent.
- The absorbent surface absorbs and spreads condensate during steam sterilisation reducing the wet pack phenomenon.
- Also provides the opportunity to make significant reductions in drying times particularly where extended times are used.
- Patented

Construction



Absorbent layer substantially polypropylene with 'natural' fibre inclusion

Transportation Wraps



The final product that has been introduced recently is Transportation Wraps, which is not designed to be a barrier wrap at all but just a wrap to protect the inner barrier layer (or layers). This is produced from Pure Spun banded Polypropylene and in our case is identified from the barrier wrap products by it's purple colour. This can also be provided with an absorbent layer in the same way as the SMA barrier product.



Wrapping Products

- Crepe papers
- Softened Crepe Paper
- Reinforced crepe paper
- Wet laid non woven materials
- SMS products
- SMMS products
- SMA products
- Transportation Wrap Products

Quite frankly this is now an amazing array of wrapping products which we can briefly list again:

Crepe papers

Softened Crepe Paper

Reinforced crepe paper

Wet laid non woven materials

SMS products

SMMS products

SMA products

Transportation Wrap Products

Packing Methods



All except the last item conforms to EN868 and most of them to parts 1 & 2. We wanted to work out how to use these products and which ones would perform best with the wide variety of instrumentation in use today. We wanted to establish the advantages of simultaneous wrapping as opposed to sequential wrapping and work out which other wrapping techniques were best. We had no preferences, although we admit to some preconceived ideas.

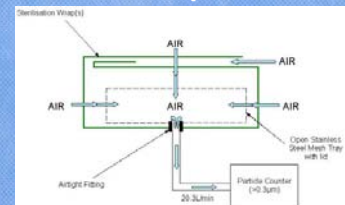
Pack Integrity Testing



Concept

- With SMTL Laboratories, attached to Princess of Wales Hospital, Bridgend
- Particle test down to 0.3µm
- Bacteria have similar particle size 0.3µm - 25µm

Test Method (Schematic)



- 1 cubic foot per minute of air
- Count particles within sizes
 - >0.3µm, >0.5µm, >1µm, >5µm, >10µm, >25µm
 - 1 minute purge
- 5 separate 1 minute sequences

The diagram shows the test more clearly.

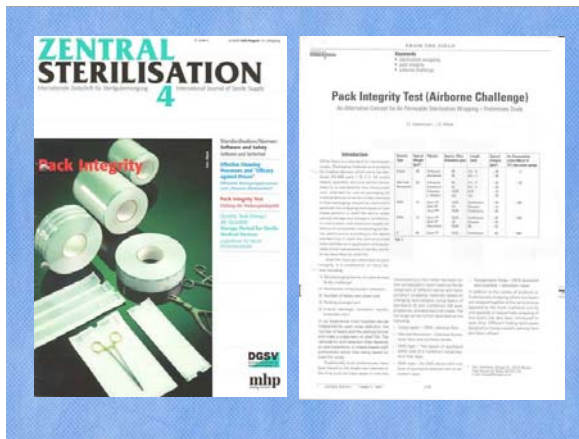
Calculation of Barrier Efficiencies

$$\frac{(A - B) \times 100 \%}{A}$$

A = Background Count
B = Count through Pack

Wraps - Generic Types

- Crepe Paper - 100% cellulose
- Wet laid Nonwovens - cellulose & polyester fibre and binder.
- SMS type - Two layers of spunbond (S) polypropylene either side of a Meltblown (M) polypropylene filter layer.
- SMA type - As SMS above with one layer of spunbond replaced by absorbent layer(A).
- Transportation Wrap - 100% spunbond polypropylene (also + absorbent layer (A))



Full details of the test would form a separate presentation and has been presented to the UK Sterile Services Club and published in the European Journal.



Typical results with single envelope packaging are shown.

These results predictably show:

SMS types (Choice Wrap) as a good barrier

Wet Laid and crepe paper as poor performers

Linen as a poor barrier

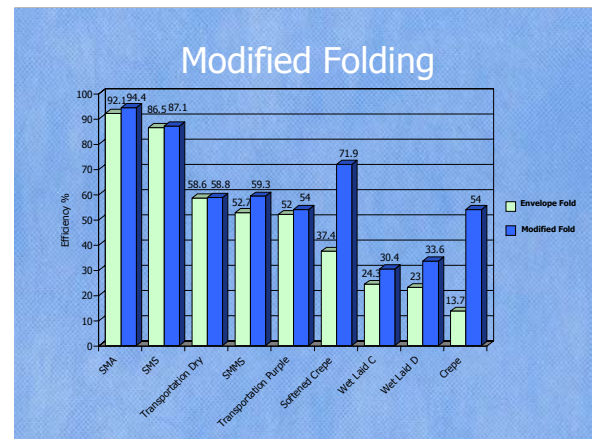
In the case of Choice Wrap, we know that Choice Dry has a higher barrier level (melt fibres) than the standard Choice Wrap and our test is picking up this difference.

The SMMS product we looked at, probably had two very lightweight melt fibre layers giving inferior filtration compared to Choice products.

It is interesting to note that the Purple Transportation wrap performs better than the 'approved' wet laids and crepe paper!!



We therefore decided to change the folding techniques and modified the folding as shown here. This additional tuck is often used when two layer/simultaneous packing is used.



Again the results were surprising.

Choice wraps changed very little and remained superior.

Wet laids changed very little but remained inferior

However, crepe and reinforced crepes improved considerably

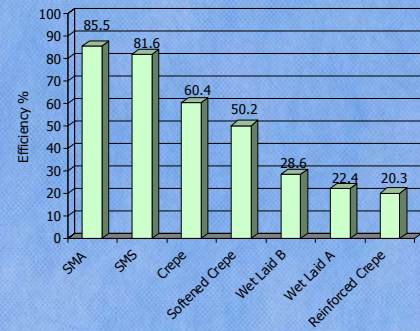
Particle Penetration Test



In order to try and understand this even further, we decided to develop a new test capable of testing just the particle penetration through the wraps and eliminate the variations created by different folding techniques. This has led us to develop our particle tester, with an inverted pyramid to which we can seal a 50 x 50cm sheet.

Through this sheet we can withdraw the air and measure through the particle counter just as before.

Particle Penetration Test



Again the results are in the same order as before, with Choice Dry and Choice at the top and the wet laids at the bottom!!

Fibre Dimensions

Fibre	Diameter	Max. Diameter	Length	Shape
Softwood	50 um		2.5 – 5mm	Fibrillated
Hardwood	20 um		0.5 – 2mm	Fibrillated
Polyester 1.7 denier	15 – 20 um		6 - 12mm	Cylindrical
Meltblown PP	2-6 um	10 um	Discontinuous	Cylindrical
Spunbond PP	15-25 um	50 um	Continuous	Cylindrical

To try and understand the reasons for this, one needs to understand the fibres used and the construction of them.

This chart lists the various fibre sizes.

Crepe paper is constructed of pure cellulose. These fibres can be fibrillated, less so in reinforced crepe, to provide strength and other properties. Air passage through such products will be more restrictive but filtration could be effective. It is clear however, that packing methods are important with crepe paper, because the air will be drawn through the route of least resistance, which may be between the folds.

Additional folding and layers will enhance the performance of pure cellulose products. This certainly accounts for the poor results in the pack integrity test.

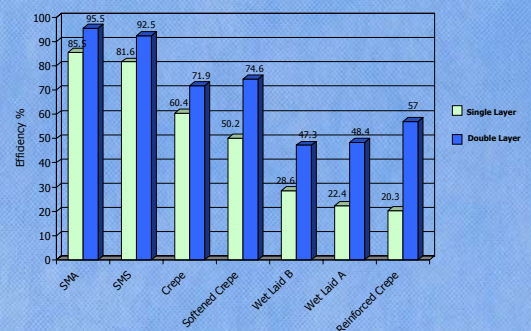
The same rules would apply with the reinforced crepe papers, but the slightly inferior results can be explained by reduced fibre treatment, additional off-machine creping, which while softening the product may break some fibres, all reducing the filtration effect.

Wet laid nonwovens are produced with polyester fibres which are thick and usually cut to 6mm and 12mm. They are designed to mix well with the cellulose fibres in the wet manufacturing process. However, they tend to increase pore size thereby reducing the filtration effect of the product because of their large diameters.

Choice Dry and Choice Wraps are produced with strong spun bonded fibres and enclose the very much finer meltblown fibres. These meltblown fibres are extremely fine and short. With good dispersion and in the right quantity, these provide excellent filtration with rapid penetration of gasses – just what is needed for the autoclaving process and for maintaining sterility.

Transportation wraps, based on spun polypropylene fibre will vary greatly depending on the fibre denier and formation, but some filtration effect is certain and possibly superior to crepe papers, when folded and used as a wrap.

Double Layers



Under the particle penetration test, the air can only pass through the product and not escape through folds as in the pack integrity test, but the pattern remains the same. Again the Choice and Choice Dry changed very little as the spun in a single layer already performs so well.

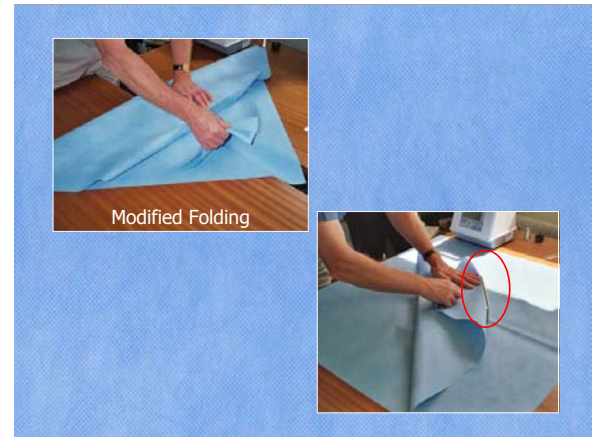
However, cellulose-based crepe papers and reinforced crepe paper improve greatly.

Wet laids still remain the worst performers.



Therefore we conclude that an inner layer of Choice or Choice Dry and one layer of Purple Transportation Wrap will provide excellent barrier protection with the inner wraps and excellent handling properties from the outer transportation wrap.

As we cannot yet claim any barrier properties for Purple Transportation Wrap, we would probably suggest that...



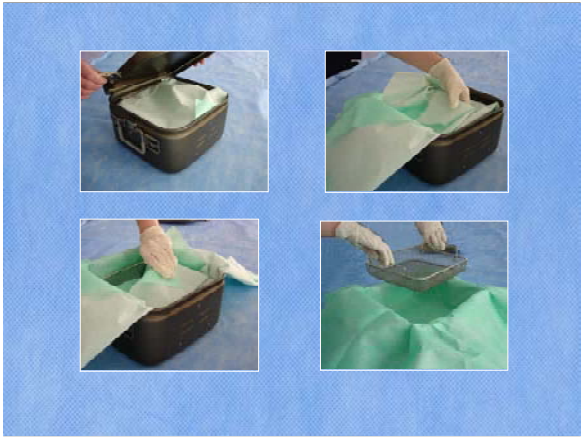
...modified folding is used for the inner barrier layer to eliminate any risk of contaminating the outer edge of the tray on opening.



Changing to purely synthetic material for packaging can also exacerbate the wetness problem during autoclaving, but this can be overcome by using the absorbent 'Dry' feature exclusive to Clinipak either in the form of Choice Wrap Dry (inner wrap) or as Purple Transportation Wrap Dry (outer wrap).



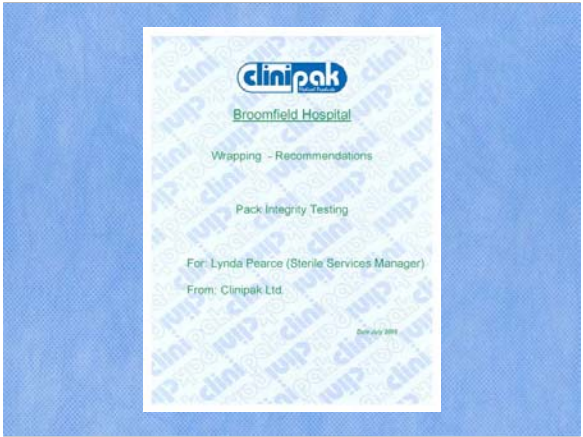
Bags can also be offered for the outer wrapping and this is mostly provided in the Purple Transportation Dry or Plain.



Remember also that Choice Dry may also be used to wrap inner baskets in containers offering safe tray removal and an excellent product to obtain dry autoclaving cycles.



It has occurred to us that our pack integrity test offers us a chance of rating a hospital's current wrapping style as well as materials.
If we are asked to make a change using our materials we can do so and produce comparable results.

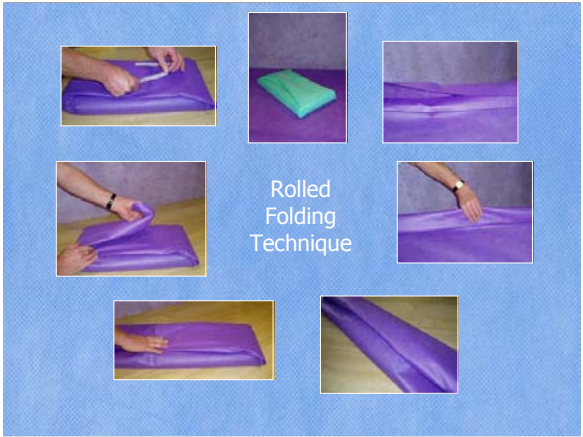


In June of 2005, we were invited to rate all of the packing methods and materials used in this hospital.

Broomfield Current Practice

No	Description	Wrap 1 (inner)	Wrap 2	Wrap 3 (if any)	Normal Sheet Size	Normal Tray Size
					cms	inches
1	Orthopaedic	Green Choice	Blue Choice Dry	Purple Trans. Dry	100 x 150	21 x 10 x 5 (container)
1a	Orthopaedic	Green Choice	Blue Choice Dry	Purple Trans. Dry	100 x 150	18 x 12 x 2
2	Broomfield (Theatre)	Crepe	Crepe	Crepe	100 x 140	18 x 10 x 2
2a	Broomfield (Theatre)	Crepe	Crepe	-	100 x 140	18 x 10 x 2
3	St John's (Theatre)	Green Wet Laid	Blue SMS	Purple Trans. Dry	100 x 140	18 x 10 x 2
3a	St John's (Theatre)	Green Wet Laid	Blue SMS	Purple Trans. Dry	90 x 90	12 x 12 x 2
4	Maternity	Green wet Laid	Blue SMS		135 x 150	18 x 18 x 2
5	Plastic OOD	Green Wet Laid	Blue SMS		90 x 90	12 x 12 x 2
5	Day Stay	Crepe	Crepe	Crepe	100 x 140	18 x 12 x 2

Their current packs can all be summarised in this chart.



We noted that a conventional parcel fold inner was used but that the outer wrap is always rolled folded as shown here.

We also took note of the indicator tape and the position used on the pack.



Finally, we scaled all this down to suit our laboratory test tray size and ran the test.

<u>Pack Integrity results of Current practice</u>						
No	Description	Wrap 1 (inner)	Wrap 2	Wrap 3 (If any)	Integrity (%)	Sheet Size
1	Orthopaedic	Green Choice	Blue Choice Dry	Purple Trans. Dry	97.10	1000 x 1000 mms
1a	Orthopaedic	Green Choice	Blue Choice Dry	Purple Trans. Dry	96.67	850 x 850 mms
2	Broomfield (Theatre) / Day Stay	Crepe	Crepe	Crepe	84.16	850 x 850 mms
2a	Broomfield (Theatre)	Crepe	Crepe	-	84.48	850 x 850 mms
3	St. Johns (Theatre)	Green Wet Laid	Blue SMS	Purple Trans. Dry	86.23	850 x 850 mms
4	Maternity / ODD	Green wet Laid	Blue SMS		65.74	850 x 850 mms

The results on their existing products looked like this.

We felt that 1 and 1a could be reduced to two layers by running Green Choice Dry and eliminating the second layer.

Note how the crepe improved little with 3 layers.

And how number 4 deteriorated when reduced to just 2 layers without the Purple Transportation Wrap.

We therefore looked more closely at these items to identify how good the filtration properties are with them.

All followed expectations except the Blue SMS and the Green Wet Laid!

Broomfield Results and Comparisons									
No	Description	Wrap 1 (inner)	Wrap 2	Wrap 3 (if any)	Integrity (%)	Sheet Size	Possible Alternative		Integrity (%)
							Inner	Outer	
1	Orthopaedic	Green Choice	Blue Choice Dry	Purple Trans. Dry	97.10	1000 x 1000 mms	Choice Dry Green	Purple Trans. Dry	92.42
1a	Orthopaedic	Green Choice	Blue Choice Dry	Purple Trans. Dry	96.67	850 x 850 mms	Choice Dry Green	Purple Trans. Dry	94.27
2	Broomfield (Theatre) / Day Stay	Crepe	Crepe	Crepe	84.16	850 x 850 mms	Choice Green	Purple Trans. Dry	83.60
2a	Broomfield (Theatre)	Crepe	Crepe	-	84.48	850 x 850 mms	Choice Green	Purple Trans. Dry	83.60
3	St. Johns (Theatre)	Green Wet Laid	Blue SMS	Purple Trans. Dry	86.23	850 x 850 mms	Choice Green	Purple Trans. Dry	83.60
4	Maternity / ODD	Green wet Laid	Blue SMS		65.74	850 x 850 mms	Choice Green	Purple Trans. Dry	83.60
Further alternative using 3 layers							Choice Green	Crepe	93.78

We therefore put our proposals for change recommending Choice Dry Green or Choice Green as an inner wrap and Purple Transportation Dry as the outer layer.

The final pack integrity figures are shown on the right and can be directly compared to the original figures.



This is the first time any company has come up with a method for rating packing and wrapping methods and this should provide a very useful tool for hospitals' CSSD departments to rank their method of packaging as well as materials used.

Pack Integrity Testing - Airflow Rates



When presenting this work earlier, air flow rates have been stated as being vital to the performance of the particle test. We wanted to see if changes affected this. We are unable to change the flow rates on the Particle Counter, which is fixed at 28.3 litres per minute.

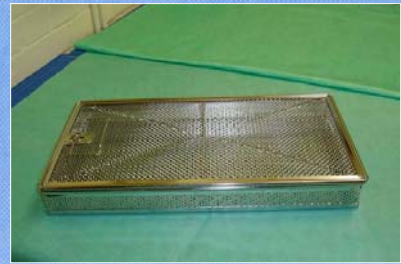


But by using three different sized trays we were able to test surface flow rates as follows:

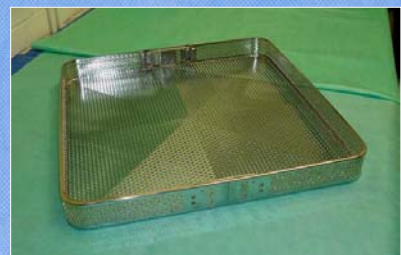


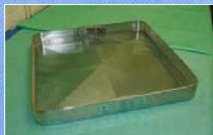


Tray A Surface Area 1722cm^2
allowing 16 cm^3 of air per
square cm per minute



Tray B Surface Area 3048cm^2
allowing 9.3 cm^3 of air per
square cm per minute





Tray C Surface Area 5620cm²
allowing 5cm³ of air per square
cm per minute



The packing method was important and we decided to use a rolled fold technique consistently in each case.

Results

Grade	Tray Size		
	A	B	C
SMS	67.09	71.21	78.48
SMA	85.16	85.52	87.28
Wet Laid	24.88	35.87	31.10
Crepe	59.71	50.53	31.66

We repeated the tests using Crepe, Wet-Laid Non Wovens, Choice Wrap and Choice Dry. Results were as follows:

These results support our test and previous results entirely.

The Choice grades show a gradual improvement the lower the flow rate (i.e. a reduction in the ramming effect).

Crepe paper however (which we have already shown allows more air through the folds than through the paper) shows a deterioration which can be attributed to the greater length of folded wrap and therefore greater opportunity to be drawn through folds.

Wet Laid non wovens seem to show no improvement one way or the other!

Therefore, we believe that the SMS/SMA type products with good and effective meltblown PP layers will give even better performance when exposed to lower flow rates and therefore our existing pack integrity test and particle test with the higher flow rates can be used safely as a reliable performance indicator.

