Medical Packaging

Sterile Barrier

Brief

To design a system enabling sterile devices to have the quality sterile barrier checked quickly enabling only sterile products to be used.

The active packaging allows fulfilment of the brief in two ways while improving upon other aspects in the redesign.

The design allows the user to easily determine whether the package still has its sterile integrity. It achieves this in two ways - the package is under low pressure causing the Tyvek film to be concave giving a the user touch based feedback on sterility. Secondly the pack contains a titanium nanoparticle indicator which when in the presence of oxygen will turn black. With the pack under low pressure with an inert gas contained within the indicator will not show. However should the pack have a hole in, oxygen will reach the indicator and show the pack as not sterile.

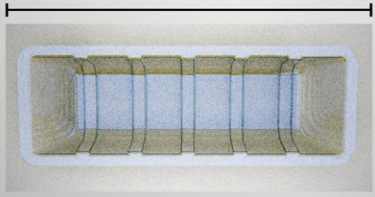
The speed at which this can be determined is very much improved over the previous as many can be checked at a glance as there is a significant visual indicator to work with. **This leads the product to minimise avoidable risk.**

The packaging process itself will contain two extra steps over previous pouch style packages, firstly it will have an extra step to add the indicator tab to the inside of each tyvek film, secondly the gas in the packet must have no oxygen and be placed under low pressure - both tasks often happen in similar assembly lines so adaption is feasible. The design is very similar to that of a packaged meat product.

Interviews with medical students 5th and 4th year have enabled a real user evaluation which when compared with perceptive evaluation had very comparable **scores of 68 & 67 /73.**

"packaging was extremely clear and obvious at a distance, with sterile barrier checks being able to be done at speed" - Katy -5th year medicine student.

The design process model of Walker's Total design [1] worked well to keep work in the correct stages and address re-evaluation at each stage.

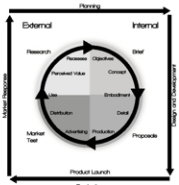


Unsafe

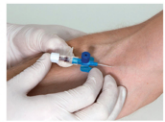
Safe

Medical Packaging
Policy, Problem & Spec

Walker's (1989) design process model will be implemented during this project, the model promotes re-evaluation as well as implementation of external ideas and processes from the designer.



The model will help implement design process and policy throughout, enabling focus on key areas to create a stronger more effective product, fulfilling a larger proportion of the design specification to a high standard.



Policy - Incorporated into this project will be the needs of the user, with the aim focussing on improved product quality and better function than the previous package designs. This will enable the product to be chosen over its competitor because of reduced likelihood of mistakes.

There are many ISO standards to conform to detailing exactly what the product must achieve and steps to make sure that it happens.

Along with quality control standards such as ISO 9001 and ISO 13485 (medical devices) it is likely that the product must also conform to more specific standards such as ISO 15378 - primary medical packaging quality control as well as requirements for sterile barrier systems for items required to be sterile until the point of use (ISO 11607 - 1:2006)

Problem

Reference [1] shows the need for a quick and easy method to check whether the sterile barrier of a medical product is in tact before its use within a hospital.

Products such as syringes, dressings and needles are routinely used and needed quickly with staff struggling for time to check the quality of the sterile barrier before rejection or use - particularly in items used in surgery.

The literature also describes the need for the package to be opened maintaining the products sterility e.g. by staying in the sterile field [1].

The most common problems with packages come from "fractured thermoforms" as well as breaks in the pouches such as pinholes slits and cuts [2], which may come from handling, transportation and storage.

Specification

Requirement	Priority	Priority Score	Method of Testing	Evidence
Provide easy sterility barrier check procedure	10	/10	Questioning of users	Analysis of user response
Maintain product sterility	10	/10	Check air sear (burst test/vacuum test)	Air leakage
Allow product to be kept in the sterile field	10	/10	Product use, opening of product and control of internals	Ability to maintain control subjective scores given
Can be opened using surgical gloves	10	/10	Use of gloves to manipulate packaging	Ability to open, subjective scores given
Quick and straightforward to use	8	/8	Timed comparison with existing products	Times comparable
Conform to relevant ISO standards	8	/8	Examination of ISO standards and comparison with new packaging	Product conforming to ISO standards
Provide Relevant Labelling	10	/8	Comparison with normal product labelling	Standard or congruent information included
Maximise Sustainability	7	/7	Analysis with existing solutions and sustainability guidelines	Material choices justified against guidelines, packaging similar or less than previous designs

[1] http://www.medicalpackaginginnovation.com/author.asp?section_id=3128&doc_id=562004& , [2] http://medicaldevicessummit.com/Manufacturing/News/Device-Packaging-Top-10-Mistakes--50.aspx

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Ideation

Ideas were created with an aim to solve the problem outlined in the brief. Using user assinged values these can be evaluated against the specification.

Two stands of design exit for this brief:

1. Packaging designed to resists punctures and tears more effectively than the previous pouch designs.

2. A visual indicator design to enable easy recgnition of packaging integrity failures - such as a reactive label.

Relating back to Walkers design process - perceived value and reassessment slightly altered objectives these have been found to be the use of these must be quick, easy, foolproof and understandable. Also linked is the evaluation and re evaluation system against specification.

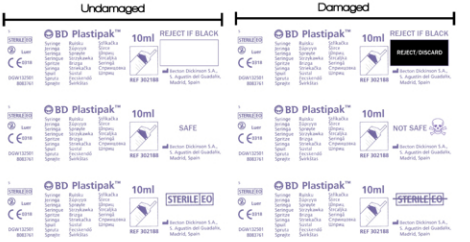
Requirement	Priority	Priority Score	1	2	3	4	5
Provide easy sterilty barrier check proceedure	10	/10	4	8	6	6	4
Maintain product sterility	10	/10	10	10	10	10	10
Allow product to be kept in the sterile field	10	/10	8	10	10	10	8
Can be opened using surgical gloves	10	/10	6	5	7	5	5
Quick and straightforward to use	8	/8	6	6	6	6	5
Conform to relevant ISO standards	8	/8	8	8	8	8	8
Provide Relevant Labeling	10	/10	8	8	8	8	8
Maximise Sustainability	7	/7	4	4	5	6	7
Total /73			**54**	**59**	**60**	**59**	**56**

Alhough design 3 carries a higher score - reassessment has shown the need for a more versitile packaging shape which is why the design to take forward will be design 2 with aspects like an easier tab opening system

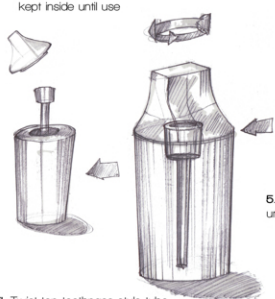
Labeling:

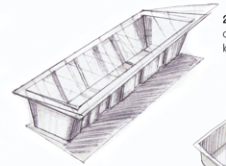
Top right shows a series of labels with minimal change to the existing information it was possible to create a section to show if the device was still sterile. Typically this could be done with an oxidising colour change dye which - if the product could be pachaged in a vacuum or alternative gas could then change should the packet receive a puncture. The clearest and easiest to interpret of the designs is design 1 as it features the largest section of change with the reject text showing against the black only when unsafe. It may also be useful to include the danger symbol as described in ISO 1415 - skull and crossbones in a triangle.

Labeling can also play a part in the use of the packaging and whether the user can determine if the product has lost its sterility. Ideation looks at reactive and active labeling to to imrpove the design

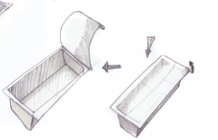


1. Twist top similar to saline vial product kept inside until use

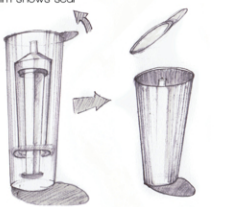




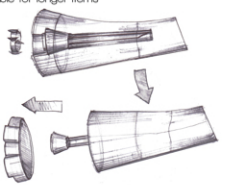
2. Vacuum formed tray, Seal checked with negative bulge from low pressure interior



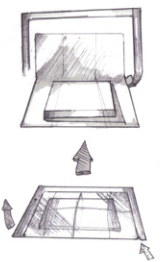
3. Package under low pressure concave film shows seal



4. Twist top toothpase style tube suitable for longer items



5. Sealed perforated bag fiddly under use but minimal material



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Product & User Analysis

Items contained withing these sorts of pouch packet need to contain information regarding the item packaged within. Typically as with the example on the left, this will be:

- The name of the device in many languages.

- A graphic should the name not translate to the user.

- Manufacturer information.

- Markings such as the CE mark and sterile mark.

Typical products that require terminal sterility are extremely numerous and can range from surgical tools to syringes.

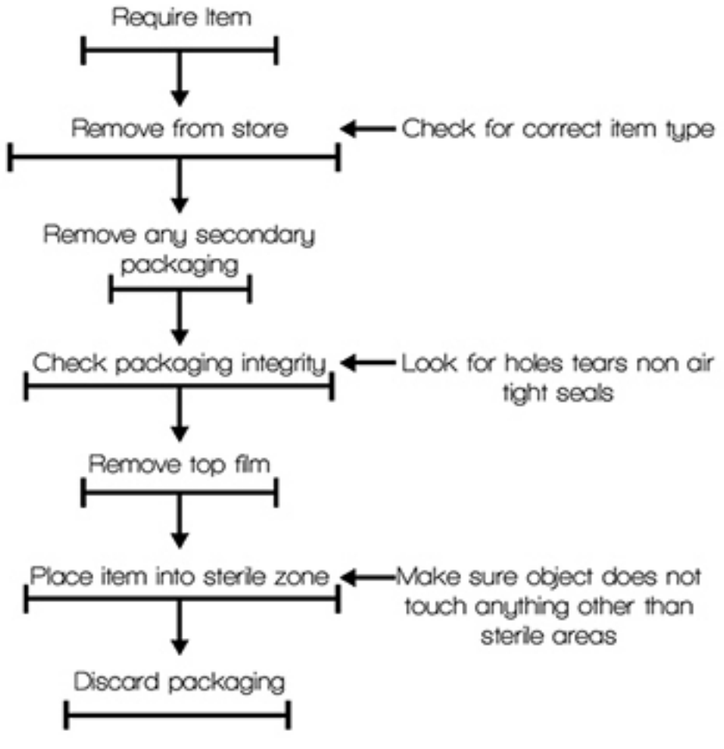
The dressing pouches (left) feature a large overspill in-between the heat seal and the dressing - this allows the heat from the sealing process to not affect the dressing. The product is contained within the thermoformed pouch this plastic is slightly thinner than the surrounding sealed section.

Much of the time they will be packaged in a pouch consisting of a thermoformed flexible bottom half and a top heat bonded to the flange of the thermoform following its product insertion.

Items in packaging must be designed in such a way that they must have rounded edges to resist pin holes together with flash from the moulding process minimised.

The outer must be a suitable size as a to maximised radius to allow better forming into the mould cavity and a more consistent film thickness along the weakest part of the package - the walls and corners [3].

Soft systems modelling of medical packaging use



Product Lifecycle

Product users consists of mainly doctors, nurses and theatre nurses all of which will be wearing latex gloves and require either immediate use of the product or control of the product so that it may be placed in a sterile zone.

Using soft systems modelling it is possible to gain an idea into the process of a theatre nurse using a piece of sealed sterile medical equipment.

Item choice must be quickly guaged under pressure as does the sterile barrier check. In the operating theatre these will be under significant time pressure, even more so in the emergency room. The item packaging must also be suitable so that when the product is removed it can be controlled and removed without nessesarily touching the insides.

[3] http://www.oliver-tolas.com/downloads/KAZ_Med_Pkg_Supp_Article_10_08.pdf

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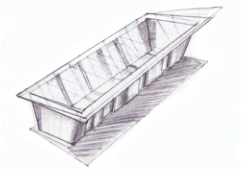
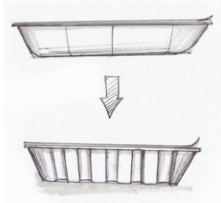
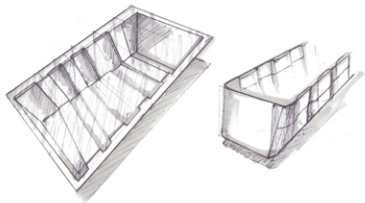
Concept Development





Taking design 2 it was possible to make a few improvements straight away.

The design relies on low pressure to give the first signs of the product not being sealed - by the concave "sucked in" nature of the of the film lid. In order to be low pressure the container must be rigid - to withstand crushing. For this a greater number of ridges have been added over thickening (adding) material.



Once ridges were added manufacturability became an issue - to aid this draft angles and fillets were added to enable problem free vacuum forming.

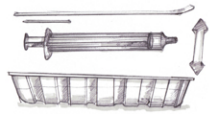
At this point sustainability can be addressed - minimising the designs plastic use by further filleting areas not needed by the housed product - this means plastic used has to stretch less and therefore a thinner type can be user.

[4] http://www.rsc.org/chemistryworld/News/2011/November/11111102.asp

To make the pack easier to open particularly for those with gloves a small section of the edge has been removed so a finger and thumb can easily be placed onto the film.

Edges of this will be rounded to avoid packs puncturing neighbouring one in transit.

Construction



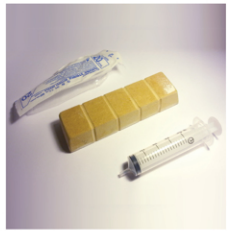
At pre-prototype stage the construction is as follows:

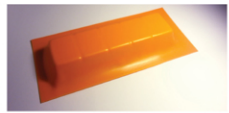
- Printed polythene outer film
- Reactive label layer
- Product (such as syringe or dressing)
- Vacuum formed polystyrene base

Mould Prototyping

The shape chosen lends itself to being vacuum formed as a means of manufacture. To check the basis of the design a simple wooden form was created to be the positive of the mould and 1mm polystyrene formed around it.

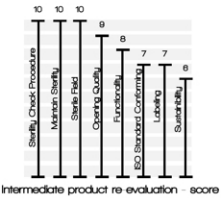
This plastic is thicker than would be used in manufacture meaning the form hasn't taken quite correctly - as tight to the mould as hoped. Details such as the ridges worked well and it is believed that the mould would work well if taken into production scales.





Active packaging exists in its trial form detecting the precense of oxygen in meat packaging. The technology consists of titanium nanoparticles coated with a methylene black dye, these are photobleached before placing into the package.

This can be repurposed in medical packaging - if the container is flushed through with a filler gas or vacuum. The nanoparticles would only be present in the printed areas , the rest being coated white - with the discard/reject design showing only when in contrast to the black



Intermediate product re-evaluation - score - 67/

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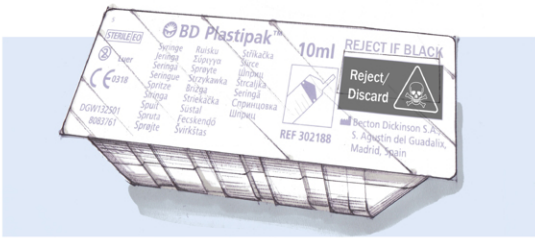
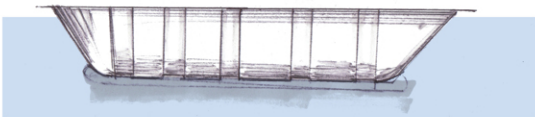
Concept Visualisation





Hand renders show the final design before CAD modelling and any further changes to aid manufacture

Also shown is the labelling placement as it would be on a normal syringe box aiding users acceptance as the design apart from the active section will be familiar and understanding of the contained item straightforward.

The label film and case are bonded using the normal method of heat sealing detailed in ISO 11607.

To pass this ISO the package must pass several tests - the most relevant in this case are the burst test and the peel strength test - making sure the package can withstand rough transit and carriage.

Items to add to packaging include:

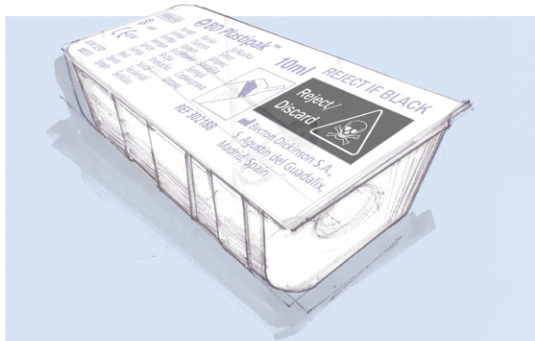
- Recycling information

- Areas for quality control and batch stamping

- Further details on the active label

When asked the comparative speed of sterile barrier diagnosis -5th year medical student Katy stated that the difference with the label was many fold with the ability to immediately tell the difference between the two labels - sterile and non sterile.

It is believed that this method will be effective on other shapes and sizes of design so long as the active section is kept in proportion to the prototype and existing text.



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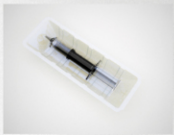
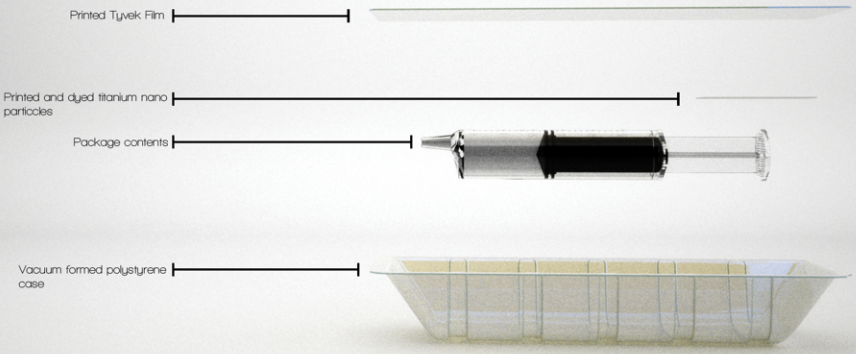
CAD Visuals

- Exploded Visual
- Inner Shot
- Product Context
- Outer Packaging





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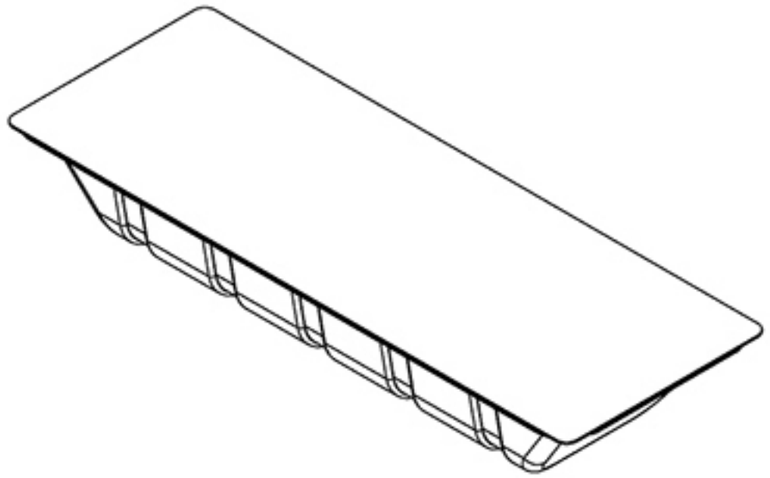
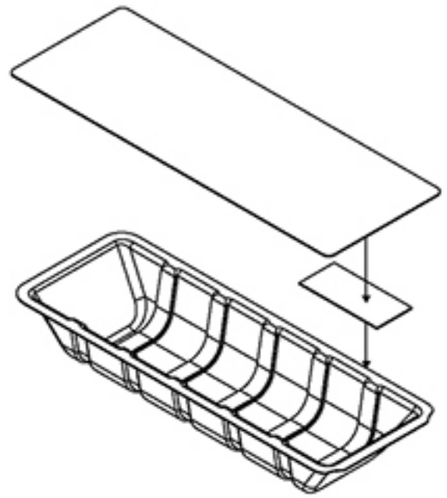
Technical Drawing

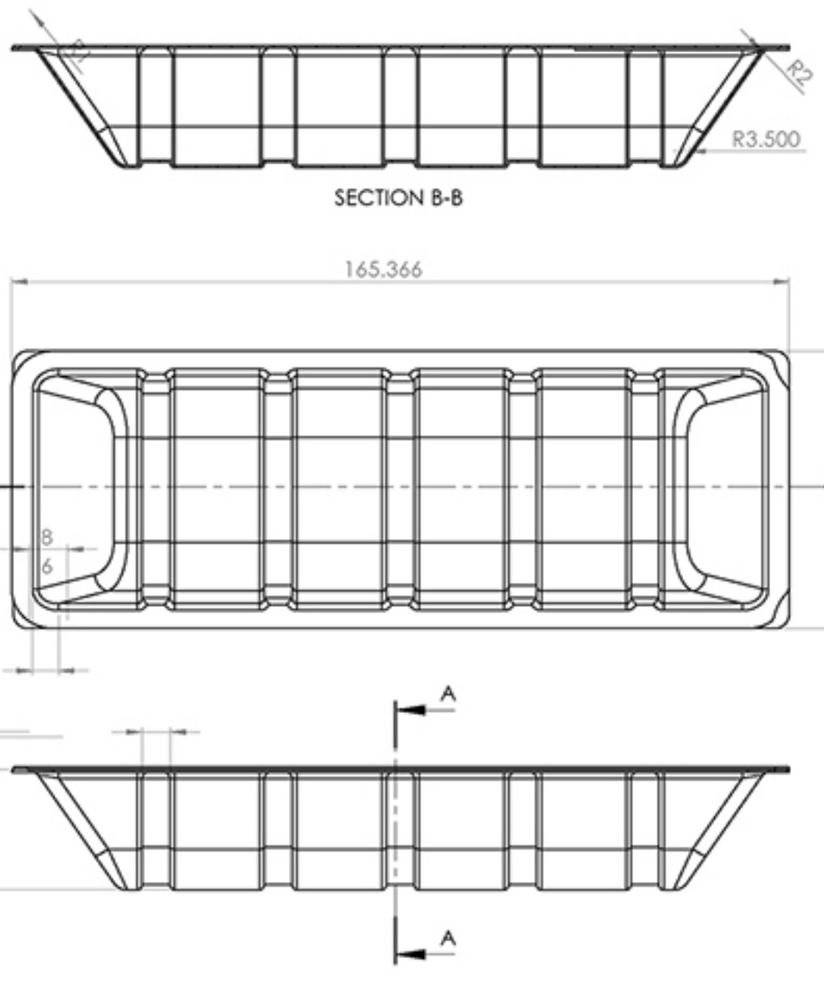
Bill of materials:

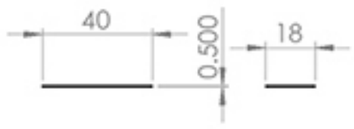
- Polystyrene Bottom 165 x 25 x 59mm
- Tyvek Printed Sealing film 165 x 59
- Titanium nanoparticles coated in black methylene dye 40x25mm

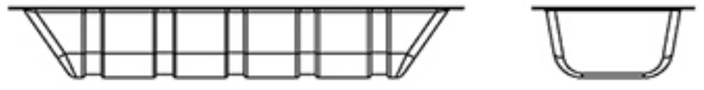
Vacuum forming has been chosen as it is the cheapest type of thermoforming that the part will allow, following thermoforming the parts wil be bonded together in heat sealing.

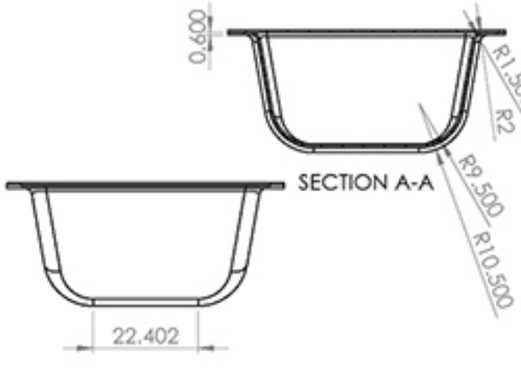












UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:				FINISH: All flashing removed		DEBUR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION
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DRAWN								
CHK'D								
APPV'D								
MFG								
Q.A				MATERIAL: Polystyrene			DWG NO.	A3
				WEIGHT:			SCALE:1:1	SHEET 1 OF 1