

maxell

MEDICAL DEVICES TECHNOLOGY

INTERNATIONAL LIMITED



EXTRACTS OF TECHNICAL FILE

RELATING TO THE HOOK-IT PRODUCT RANGE

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MATERIAL SUMMARY AND MANUFACTURING

Material:	Polysulphone
Resin Type:	TP Amorphous
Operating Temp of Manufacture:	150°C
Surface Hardness	RM69
Conformity	Medical Devices Directive 93/42/EC
Repeated autoclave cycles	100
Product Shelf life	2 years
Manufacturing Subcontractor	Maxell Europe Ltd Apley Telford Shropshire TF 6DA
Manufacturer's certificate approvals	BS EN ISO 9001:2000

J-HOOK BREAK TEST

9th November 2004

1) Test Samples

- Sample 1: PSU + Colour Master batch + Anti-MRSA (None Autoclave)
- Sample 2: PSU + Colour Master batch + Anti-MRSA (20 times Autoclave)
- Sample 3: PSU + Colour Master batch + Anti-MRSA (40 times Autoclave)
- Sample 4: PSU + Colour Master batch + Anti-MRSA (100 times Autoclave)

2) Test Method

See below

All samples were not break or stretched with maximum force of 5kg



3) Test Result

All samples were not break or stretched with maximum force of 5kg

Sample No	Force 2 kg	Force 5 kg
1	OK	OK
2	OK	OK
3	OK	OK
4	OK	OK

STRENGHT TEST FOR STERILISATION

Note: 1 kg = 9.8N however, 12.5N = 1.28 kg times

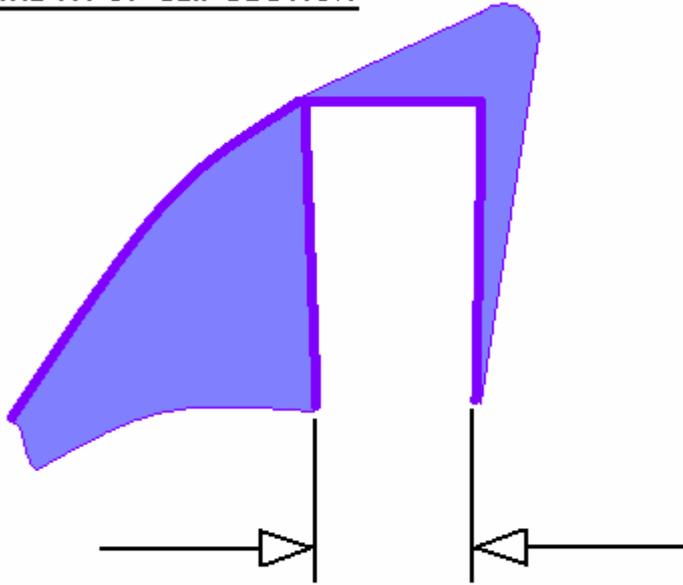
	Clip width	Number of uses			
	(see picture)	20	40	60	80
B-HOOK	25mm	25.31/24.45	25.34/24.65	25.33/24.54	25.29/24.51
C-HOOK	25mm	25.31/23.45	25.33/23.68	25.30/23.20	25.32/23.40
	25mm	25.33/23.45	25.35/23.68	25.30/23.20	25.32/23.40
J-HOOK	15mm	15.02/14.24	15.00/14.23	15.00/14.34	15.00/14.25
	Strength Test	Peaked at 12.5N	Peaked at 14N	Broke	Broke

STRENGTH TEST

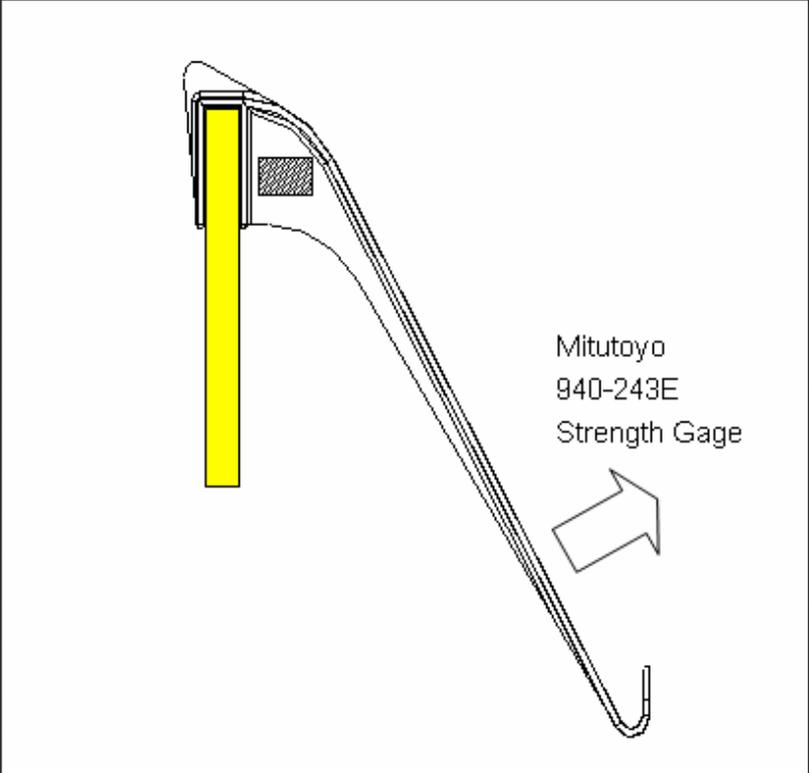
Part secured onto

medical rail section, pull force exerted using a Mitutoyo 940-243E force gauge.

WIDTH OF CLIP SECTION



Maximum and minimum of dimension.

J-Hook Holder Brake Force			
1. Method			
Using strength gage to measure break force on J-Hook.			
			
2. Result			
	15mm width	22mm width	Unit: Nm
Sample 1	11	12	} Those samples are slipped from the rail before broken
Sample 2	12	14	
Sample 3	11	13.5	
Sample 4	13	19.5	
Sample 5	15	18.5	
Sample 6	15	13	
Sample 7	13	14.5	
Sample 8	15	15.5	
Sample 9	14	17	
Sample 10	15	13	
Average	13.4	15.05	
Note: The sample are mixed Lilac master batch (6%) with Solvay PSU			

B/C-HOOK BREAK TEST

15th November 2004

4) Test Samples

Sample 1B/1C: PSU + Colour Master batch + Anti-MRSA (None Autoclave)

Sample 2B/2C: PSU + Colour Master batch + Anti-MRSA (20 times Autoclave)

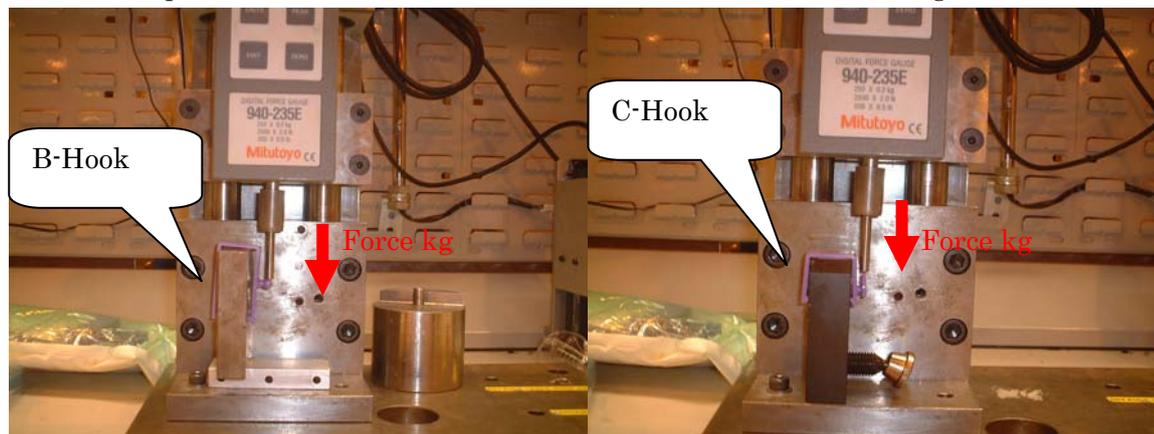
Sample 3B/3C: PSU + Colour Master batch + Anti-MRSA (40 times Autoclave)

Sample 4B/4C: PSU + Colour Master batch + Anti-MRSA (100 times Autoclave)

5) Test Method

See below

All samples were not break or stretched with maximum force of 5kg



Using MITUTOYO Digital Force Gauge 940-235E

6) Test Result

All samples were not break or stretched with maximum force of 5kg

Sample No	Bet set	Force at 10 kg	Force at 20 kg
1	B-Hook	OK	OK
	C-Hook	OK	OK
2	B	OK	OK
	C	OK	OK
3	B	OK	OK
	C	OK	OK
4	B	OK	OK
	C	OK	OK

WALL BRACKET TEST

Loads/stresses on
Test: plasterboard

Items:
Type of fixing used:

Wall Bracket & J-hook mounted on 9.5mm plasterboard
A) Nylon Self-Drive hollow wall fixings & 4.5mm screws
B) Standard plastic hollow wall fixings & 4.5mm screws

Date of test:

10/08/2005

Repetative test

Nylon Self-Drive wall plug



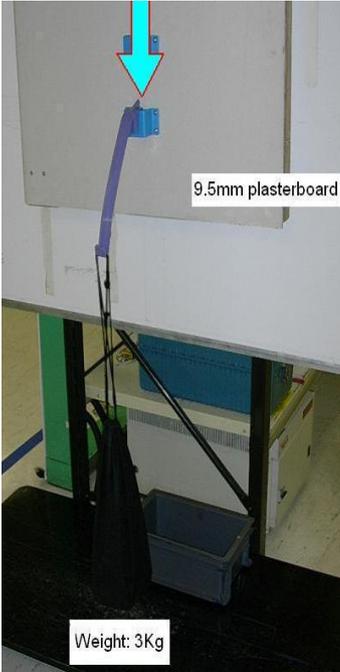
Standard plastic wall plug





9.5mm plasterboard

Weight: 3Kg



9.5mm plasterboard

Weight: 3Kg





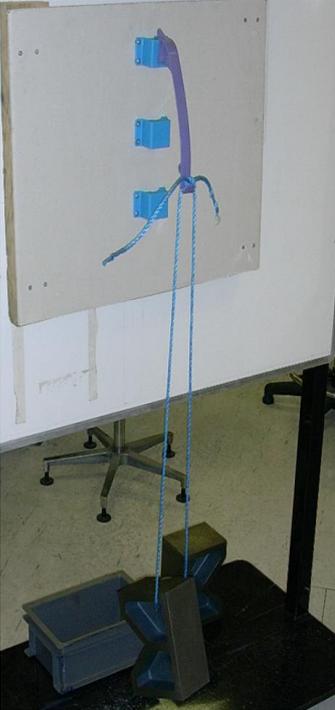


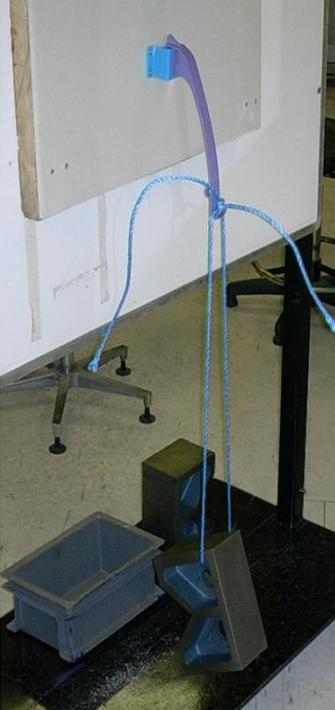


The four pictures (left and right) show the condition of the 9.5mm plasterboard after repeated loadings of 3Kg were applied.

The 'above' and 'below' views of the wall mounting show that no indentations were made on the plasterboard - with either type of fixing - at the end of the test.

Static test





10Kg load applied: Wall mount does not break away from plasterboard



Fixing type A after load of 20Kg applied



Fixing type B after load of 20Kg applied

PRODUCT INSTRUCTIONS FOR USE



HOOK-IT™ Wall Bracket

Make sure that the text on the front of the bracket is upright.

The wall bracket should be mounted approx. 5.5 ft on a wall from ground level. Position a bracket either side of a patient's bed if space allows.

The bracket can be cleaned with soap and water or alcohol.



HOOK-IT™ C-HOOK

Two C-HOOKS are to be fitted to the side rails of a bed frame in order to carry a catheter or drainage bag.

The hook can be cleaned with soap and water or alcohol. The C-HOOK can withstand multiple sterilisation cycles carried out at 135°.



HOOK-IT™ J-HOOK

Used to suspend IV and fluid bags from a wall bracket. Make sure that the text on the front of the bracket is upright. J-HOOK will take up to two IV bags.

The hook can be cleaned with soap and water or alcohol. The J-HOOK can withstand multiple sterilisation cycles carried out at 135°.



HOOK-IT™ B-HOOK

Fits on the head of the frame to carry fluid bags when transporting patients on beds.

The hook can be cleaned with soap and water or alcohol. The B-HOOK can withstand multiple sterilisation cycles carried out at 135°.

RISK ANALYSIS

Material recommendation provide by Rapra Technology report nature 40252.

The Products conform to the essential requirements of the Medical Devices Directive 93/42/EC in respect of Class 1 products. With system used for affixing the CE Mark is in conformity with the requirements of the Directive as described in Article 17 in accordance with Annex II.

The key risks associated with use of the product relate to the ability of the hooks to support the weight of any fluid bags attached to them.

J-Hooks are designed to fit onto curtain tracks around a hospital bed. Specific warnings are given on the packaging and in the literature that a maximum of 2 fluid bags can be held by each J-Hook.

Data on file at the licensor for this product (Royal Wolverhampton Hospital Trust) indicates that curtain tracks used in NHS hospitals must be able to hold at least 30kg in weight, which far exceeds any weight that it would be subjected to by suspending fluid bags (which typically weight 1 Kg each). The key risk is therefore that the J-Hooks snaps or breaks allowing the fluid bags to fall.

J-Hooks are subject to multiple sterilisation as part of the cleaning process in hospitals. To ensure safety and mitigate risks, the plastic from which the J-Hooks are made was chosen based on recommendations by an independent expert, RAPRA (see attached report).

The chosen plastic, polysulphone, is able to withstand multiple steam sterilisation without loss of material properties including strength and dimensional tolerance. The latter is important in ensuring that the fit of the product over hospital curtain rails does not deteriorate with time.

To further mitigate risk, MDTi states in the product literature and on the packaging that the hooks should be renewed after 2 years of use.

B-Hooks and C-Hooks are not subjected to the same levels of stress and weight as J-Hooks but are still manufactured from the same high-grade polysulphone material.

Break force tests have been carried out to ensure that all hooks are not going to fail in use. Two types of test have been performed.

Test 1:

This is the key test as it relates to the forces to which the hooks will be exposed during normal use (see attached sheet). J-Hooks that had been subjected to 0, 20, 40 and 100 steam autoclave sterilisation cycles were tested with no failures up to the maximum test load of 5 Newtons. This is equivalent to 5 fluid bags being hung from the J-Hook. Given that this is virtually impossible to achieve in practice and that the instructions given on packaging and literature state that a maximum of 2 fluid bags per hook is permissible, the hooks are considered to be very safe for use. The force required to cause breakage is considered to be far in excess of the forces to which the hooks will be subjected in normal use.

B-Hooks & C-Hooks that had been subjected to 0, 20, 40 and 100 steam autoclave sterilisation cycles were subjected to a test mimicking downward load with no failures up to the maximum test load of 20 Newtons. This is equivalent to a 20 litre fluid bag being hung from a single hook. Given that this is virtually impossible to achieve in practice the hooks are considered to be very safe for use. The force required to cause breakage is considered to be far in excess of the forces to which the hooks will be subjected in normal use.

Test 2:

This test is designed to mimic the forces that a J-Hook might be subjected to if being forced upwards off a curtain rail or wall bracket in an upwards direction. Effectively, this test is assessing the strength at the anticipated weak spot in this hook which is indicated on the attached sheet. J-Hooks that had been subjected to 0, 20, 40, 60 and 80 steam autoclave sterilisation cycles were tested. The test revealed that J-Hooks that has been sterilised 60 & 80 times broke at 14 Newtons and 12.5 Newtons. This is equivalent to the weight of at least 12.5 fluid bags being applied upwards. This is felt to represent little risk in practice and the J-Hooks are deemed safe for use under normal loads in use.

All J-Hook tests were conducted on 15mm samples. The 21mm sample is inherently stronger due to the design itself and therefore was not tested separately.

Wall bracket

Additional testing has been performed on the wall bracket to ensure that the bracket itself can support a fully loaded J-Hook without breakage or movement. These included repeat tests applying a load of 3 Kg (equivalent to 3 fluid bags) on plaster board partition which far exceeds the weight that the bracket will have to support in practice (2 fluid bags = normal maximum load). Multiple repetitive tests (over 1,000 repetitions) were undertaken with a 3Kg weight and the bracket fixings remained in place and firm. Appropriate motion tests were introduced to establish the effect of upward, side ward and downward stresses on a plaster board of 9.5mm thickness and the results confirmed that the bracket fixings did not pull away from their wall mounting.

Static tests with weights up to 10Kg were performed and again the fixings and wall bracket remained unaffected. Only when an excessive weight (20Kg) was applied did the fixings finally give way.

Given these results, it can be concluded that the wall bracket when fixed with appropriate fixings is safe for use.