Rebuttal of Boston Scientifics Expert Reports (DRAFT)

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Dr. Chris DeArmitt - President

Phantom Plastics

REPORT

Executive Summary

One of my previous expert reports showed compelling evidence, using different methods, that Boston Scientific mesh made of genuine Marlex® HGX-030-01 was drastically under-stabilized. *The other expert report conclusively demonstrated that the Chinese sourced PP is not genuine Marlex® HGX-030-01 and is therefore not approved by the FDA for implantation.*

The defendant's experts have issued reports refuting those two points. Their experts provide no data or arguments that change the conclusions of my two previous reports. Whereas we made our points using sound scientific methods and extensive references to the scientific literature, their experts provide little or no data in support of their claims. In several instances, their experts make statements that are demonstrably false.

In this report, we address some of the statements made by Boston Scientific's experts and provide even more citations to scientific, peer-reviewed publications to prove that PP is unstable even at room and body temperature and will fail if the antioxidant is insufficient or of the wrong type for the intended use.

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Scope of Work

Phantom Plastics LLC was retained by Mostyn Law, plaintiff's counsel, to investigate and report on polypropylene mesh regarding its properties, durability, and suitability as a material for permanent implants. *In addition, we investigated the China Sourced Resin to see whether it was genuine Marlex® HGX-030-01.*

Qualifications

Dr. Christopher DeArmitt

Dr. DeArmitt obtained a BSc (Hons) in chemistry with polymer science from the University of Sussex, United Kingdom. He then obtained his MPhil and PhD on the topic of conductive polymer colloids, also from the University of Sussex. A very wide range of analytical techniques were used to characterize the new polymers and colloids made.

He has over 25 years of industrial experience in plastics and formulation of plastics including additives such as fillers, reinforcements, antioxidants (stabilizers), impact modifiers and slip aids.

Dr. DeArmitt was Manager of the Polymeric Materials Group at the Institute for Surface Chemistry in Stockholm. He created multi-national, multi-client projects on the topics of polymers, mineral fillers and antioxidants. During that time, he worked with the KTH Stockholm to create new hyperbranched, high molecular weight antioxidants to provide extraction resistance and long-term performance.

He was Senior Project Manager at Electrolux (known as Frigidaire in the US) in which capacity he led a team to optimize Carboran, a polypropylene material which Electrolux uses in amounts exceeding 55,000 metric tons (over 120 million pounds) per year. Optimization of the fillers and antioxidant package were major topics. Later, Chris ran a project which identified new natural antioxidants for polypropylene.

As Global Product Development Manager at BASF's headquarters in Germany, Dr. DeArmitt worked on a wide range of polymers including competitor analysis, new product creation and new additives to give extended durability. Several patents resulted.

As President of Phantom Plastics LLC, Dr. DeArmitt creates new plastic materials, solves problems and provides training to well-known companies like P&G, Apple, Exxon, Disney, Total, Eaton and more.

Publications to date include 3 encyclopedia chapters, 7 book chapters, 1 book over 40 articles and 14 granted patents.

He has received most votes in internet forums, with over 14 000 members, for helping professionals with their plastic material related questions. He was elected Fellow of the Royal Society of Chemistry (FRSC) and is a Chartered Chemist (CChem).

Dr. Chris DeArmitt's curriculum vitae is attached as Appendix A.

Introduction

This report will examine the statements made by Boston Scientifics experts. First is a recap the findings and conclusions of the previous two reports. The conclusions presented are based on approximately 300 articles, book chapters, patents and other documents I have reviewed over the recent months.

Normal procedures

Having worked at plastics companies such as BASF and for consumer appliance companies like Electrolux-Frigidaire, I am familiar with how materials are designed for their end use.

When at BASF we would design antioxidant systems and test them in our plastics for many thousands of hours. The work was tedious and costly but we wanted to ensure that our products would last for decades without failure. Accelerated testing was performed to ensure that our products would last. Chemical resistance tests were done to see if the plastic would fail when exposed to liquid. Mechanical tests were performed. We even made special test equipment in-house so that we could test the plastics in situations closely mimicking the real-use situation.

Similarly, at Electrolux-Frigidaire, we wanted to make sure that our appliances, washing machines, dishwashers, refrigerators etc., would last for 10 years or more. Extensive testing was performed and we carefully designed and evaluated our stabilizer systems in polypropylene which was the main plastic used. We selected the type and amount of antioxidant to use. We measured to make sure that the antioxidant level in our products was correct. We checked to see how much of it was used up in processing the polymer. We did accelerated testing to estimate the lifetime of the product and added extra antioxidant to give us a safety margin. Lastly, we reclaimed used washing machines from customers and analyzed to see how much stabilizer had been used up in real-world conditions.

You may be wondering why I am telling you all of this because it seems so obvious. I agree, it was obvious to us. We cared about our quality, our brand image and about not having expensive warrantee claims due to failures. I am mentioning all of these "obvious" steps we took because Boston Scientific took none of those steps. I could hardly believe it when I first heard that they did not know what stabilizers were in their implantable PP mesh. They had never designed a stabilizer package for it. They had never checked to see how much stabilizer was lost when converting the PP pellets into the fibers. Most incredibly, they had never done a

single test to evaluate the durability of the mesh in the body. This is the story of a company that not only failed to provide a quality product but made almost no effort to do so.

Polypropylene is unstable to oxidation even at room or body temperature

We made the point that polypropylene (PP) is notoriously unstable. Even at room temperature or body temperature, PP will degrade rapidly due to oxidation, become brittle and lose its strength. This has been known since the 1950s when PP was first commercialized. That is why stabilizer is added immediately once the PP is made, in order to prevent the instant onset of oxidation. Incredibly, the defendants experts claim that PP is only unstable at high temperatures or under UV light. Whereas we provided hard data and citations to show that PP is very unstable, they provided no data to the contrary. I do not know any true polymer expert who does not know that PP is unstable to oxidation and I have conferred with several top experts on that matter.

In order to show that the defendants experts are incorrect, I have collected overwhelming evidence to prove that PP is unstable at body temperature and even at room temperature. A whole section is dedicated to making that point beyond any doubt. In many instances, I have added the original data, pasted in directly from the original articles, so as to avoid ambiguity.

The defendants claim that PP is "inert" i.e. unreactive but as we will show, that is certainly not the case. There is another motivation for proving that unstabilized PP fails rapidly due to oxidation. At some point, stabilized PP loses all of its stabilizer. At that point, it is once again unstabilized PP and will fail. We will discuss how that stabilizer may be lost, for example it may be used up fighting radicals or it may simply be washed out of the PP by exposure to water.

Richaud et at. reported[1] that unstabilized PP degraded in about 1000 hours at 40°C which is almost exactly body temperature (37.5°C).

Achimsky et al. showed[2] that PP began to degrade rapidly in just 3000 hours at 50°C (Figure 1).

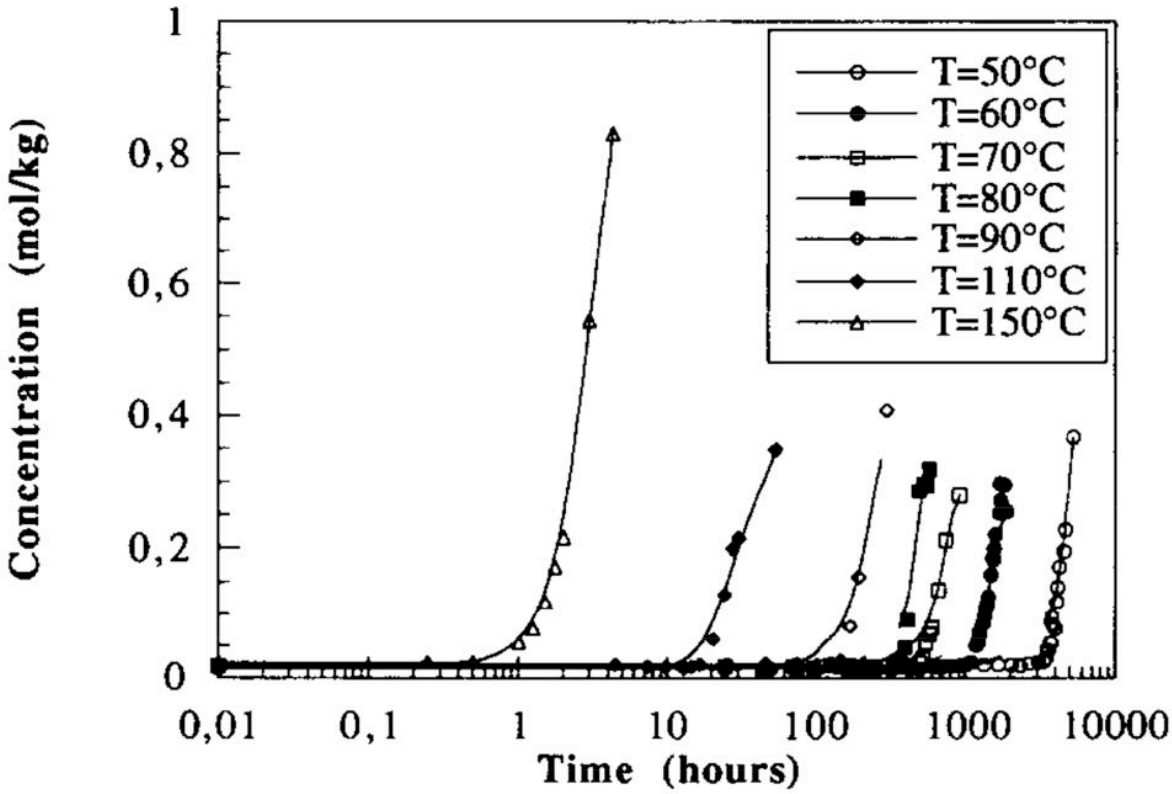


Fig. 3. Carbonyl build-up at different temperatures.

Figure 1 Rapid oxidation (shown by carbonyl build-up) of unstabilized PP begins at just 3000 hours at 50°C

Gugumus showed that unstabilized PP films failed in 300 hours[3] at 40°C, i.e. body temperature (Figure 2). The work was performed on PP films 120 microns thick, very similar to the diameter of the PP mesh fibers.

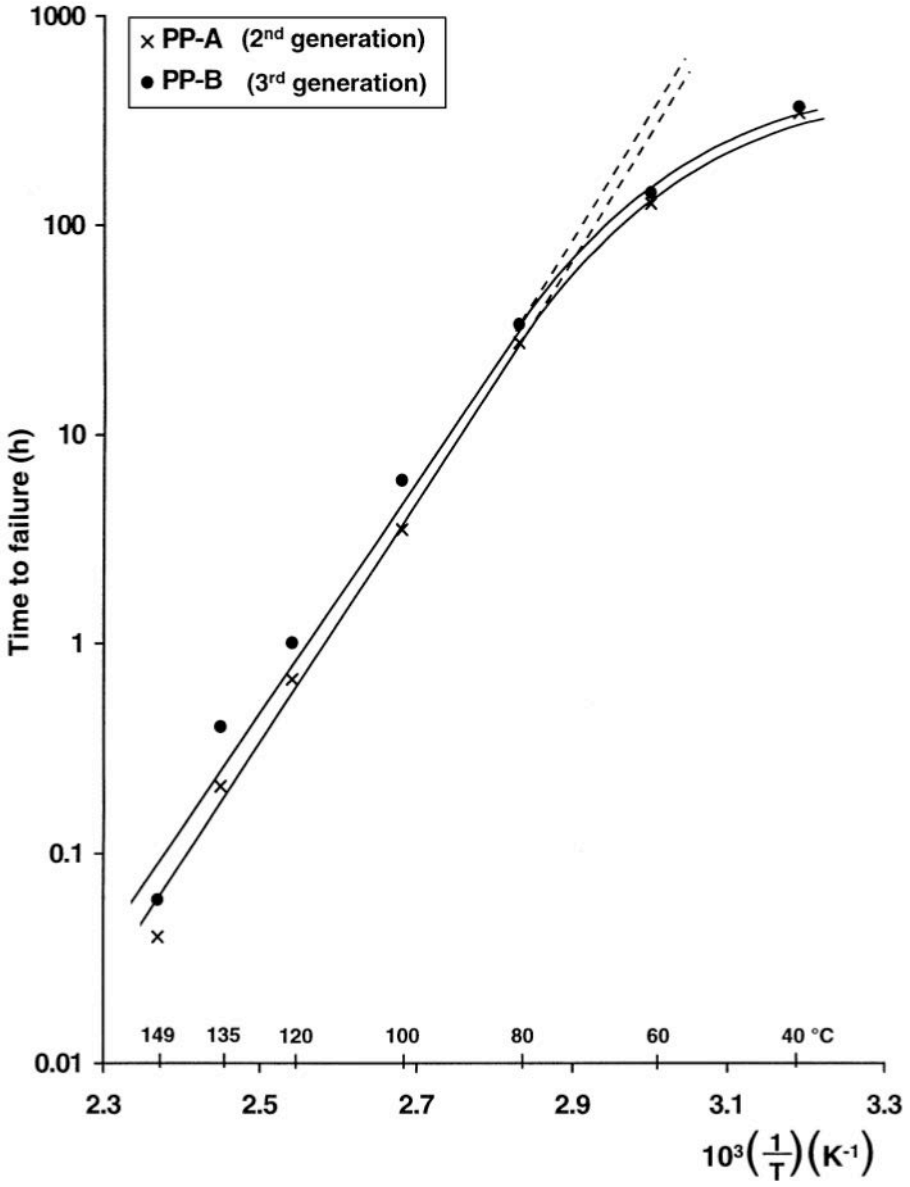


Fig. 1. Arrhenius-plot for lifetime of unstabilized melt-cast PP films (120μm).

Figure 2 Failure of unstabilized PP films occurs in just 300 hours at 40°C, i.e. body temperature

Gijsman discovered that several different unstabilized PP materials oxidized[4] between 1200 hours and 5000 hours at just 50°C (Table 1).

Table 1. Induction period (h) measured in duplicate at temperatures between 50 and 130°C for samples containing different amounts of Ti catalyst residues

Temperature (°C)	Sample containing:			
	<2 ppm Ti	8 ppm Ti	64 ppm Ti	180 ppm Ti
50	4 552	4 898	1 245	1 197
	3 978	4 861	1 275	1 172
60	2 441	2 898	781	649
	2 972	2 886	818	732
70	1 460	1 688	594	480
	1 710	1 560	480	504
80	852	850	332	237
	733	670	332	233
90	349	324	115	113
	310	309	108	85
100	101	68	39	28
	91	62	36	31
110	19	19	13	13
	24	16	13	14
120	7·2	4·6	3·9	4·6
	7·5	4·7	3·1	4·8
130	1·7	1·0	1·6	1·0
	1·5	1·3	1·7	1·3

Table 1 Four different unstabilized PP powders degraded rapidly at 50°C

Sipinen et al. looked at adding manganese to make PP degrade more quickly but their work also included a control sample without manganese (labeled 0ppm Mn in Figure 3). They found that the unstabilized PP degraded in just 300 hours at 70°C[5].

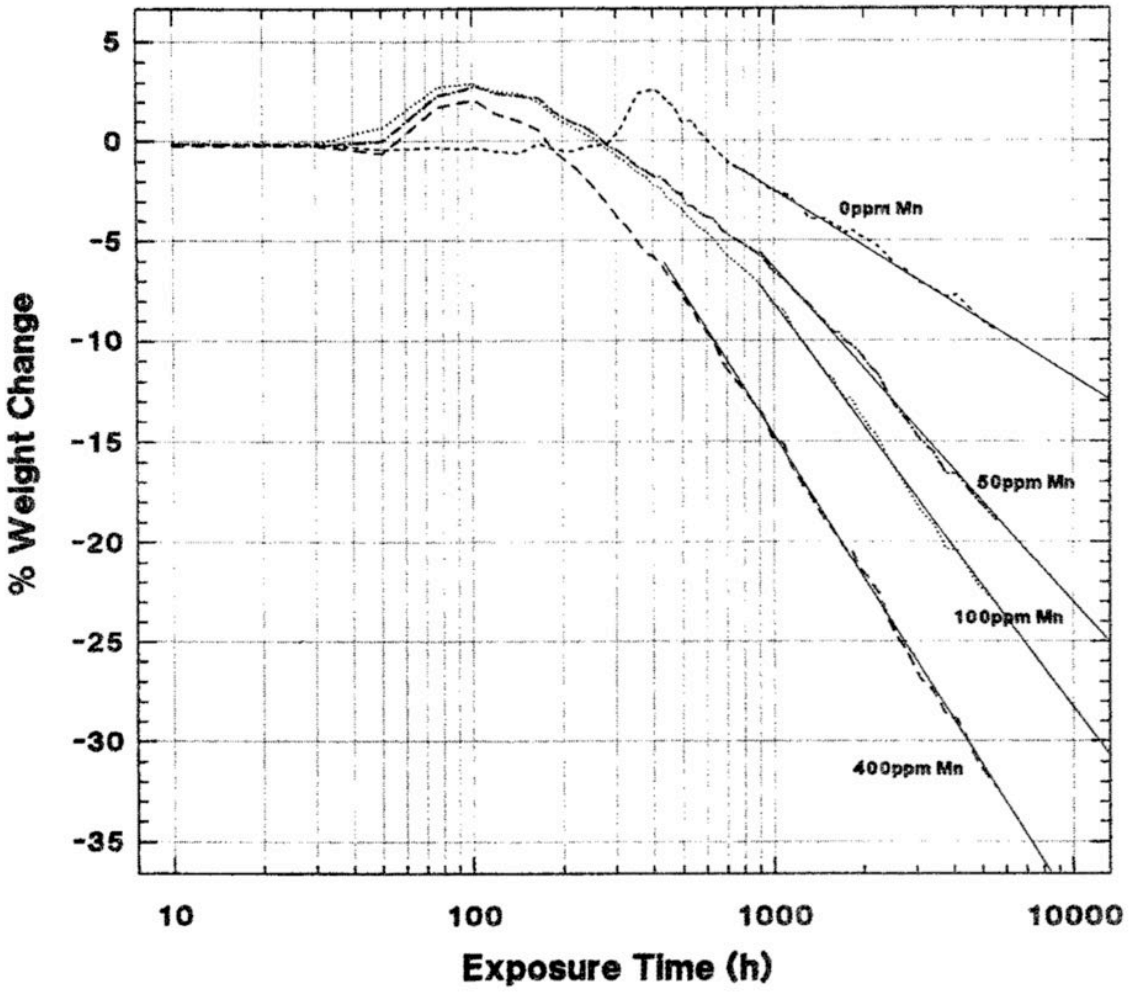


Fig. 2. Percentage weight change vs time for polypropylene films containing manganese stearate, aged at 70°C.

Figure 3 Unstabilized PP takes up oxygen and begins to degrade in 300 hours at 70°C

There are more articles showing the same message. Unstabilized PP is undoubtedly highly susceptible to oxidation at room temperature and body temperature.

Polypropylene oxidizes rapidly in water and in the body

PP is known to be unstable to biological attack e.g. by microorganisms which oxidized PP in just 50 days[6].

Another study looked at the fate of PP film buried in a landfill. The initial, smooth PP films are shown on the left and the oxidized, degraded PP films are shown on the right after just 11 months in the landfill.

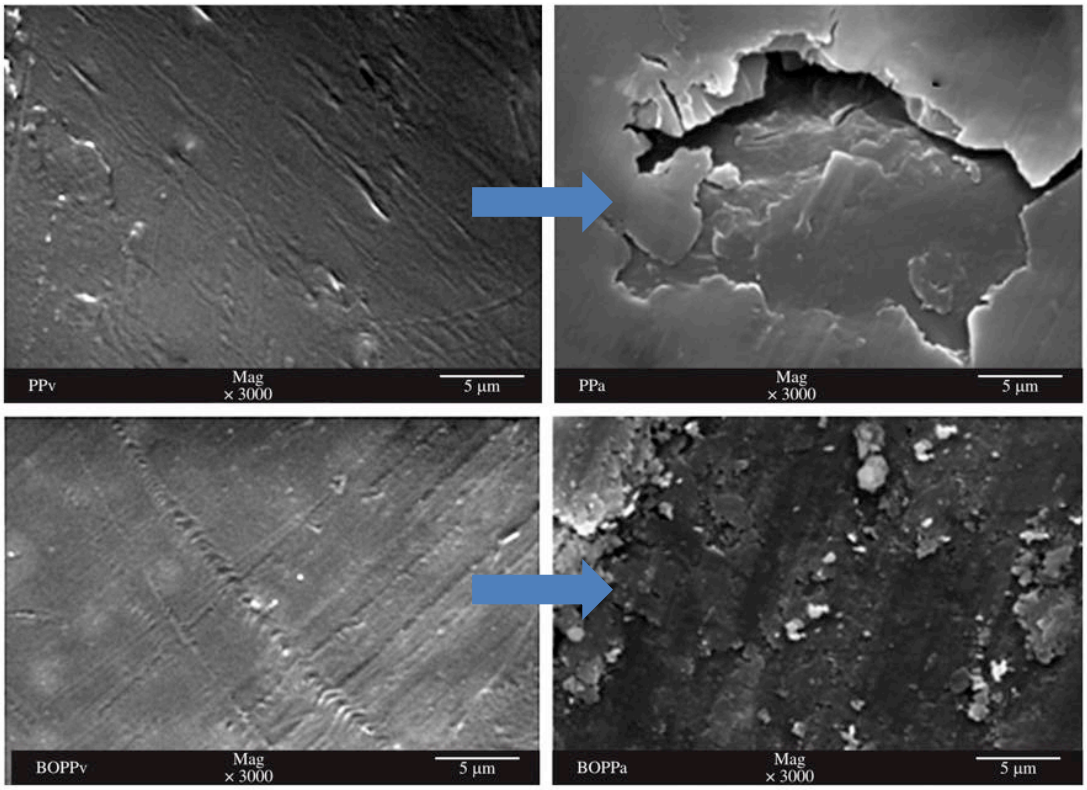


Figure 4. Micrographic (SEM) picture of the samples before and after burial in the landfill.

We also know that PP sutures lose 45% of their strength in just 7 years in the body[7]. In contrast the other suture material, PVDF, retained its strength over the same test period. This shows there are viable and better alternatives to PP.

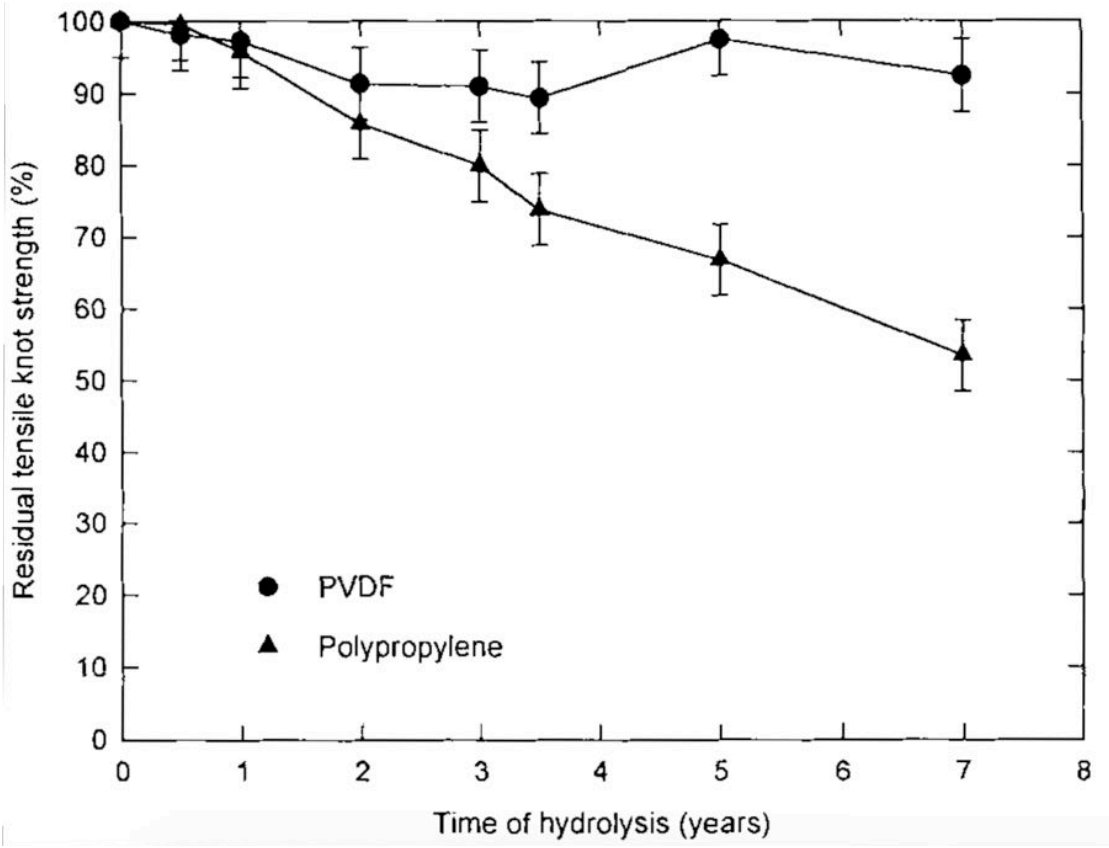


Figure 4 PP Sutures lost 45% of their strength in 7 years implanted in the body[7]

In a separate study, PP sutures lost 25% of their strength after 6 weeks implanted in rats[8]. Note that the PP sutures were of the Ethilon® and Prolene® types which contain vastly more antioxidant than Boston Scientific mesh. The elongation to break was also significantly reduced in the 6 week period. All experiments were performed multiple times to ensure that the results were statistically meaningful.

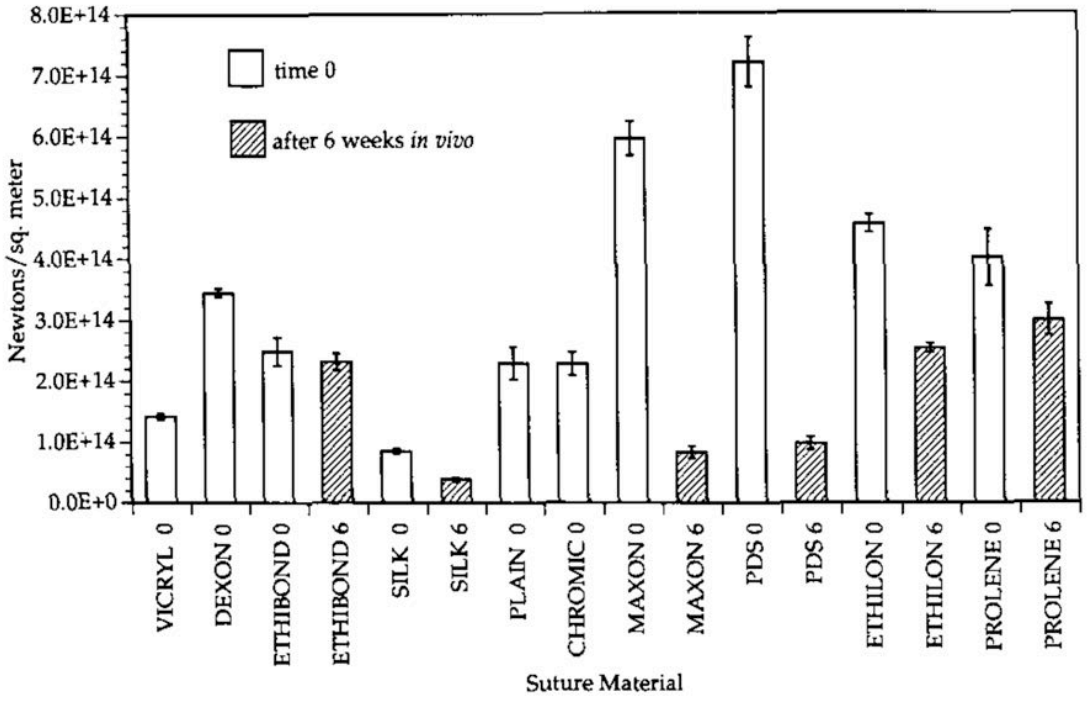
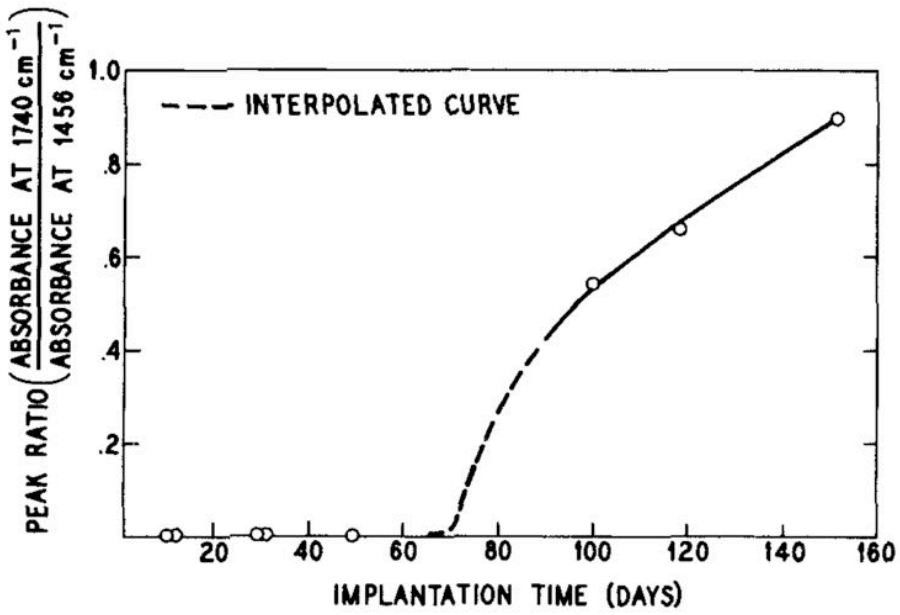


FIG. 5. Mean strength ± SEM.

Figure 5 PP Prolene® sutures lose 25% strength in just 6 weeks inside rats[8]

Of course, there is also the well-known Liebert study that originally showed that unstabilized PP oxidizes rapidly in just 108 days in vivo and that antioxidant can help protect the PP from oxidation in the body[9]. They detected oxidation by FTIR and directly observed breakage of the PP polymer chains using GPC. There is therefore no doubt that the PP was indeed attacked in vivo.



Plot of carbonyl absorbance vs. implantation time for pure PP implants.

Figure 6 Oxidation of PP implanted in hamsters with rapid oxidation starting in less than 80 days[9]

The survival of polypropylene depends on the antioxidant type and amount
Having shown that unstabilized PP is very prone to oxidation and that it will fail in 1000 hours or less at body temperature, we now look at the effect of antioxidant (also known as stabilizer). The PP will be stable as long as there is antioxidant to protect it. So, is there enough antioxidant in the Marlex® HGX-030-01?

Antioxidant is lost in two ways. First, it is chemically consumed doing its job protecting the PP. Secondly, it is well-known that the antioxidant will dissolve in the water (e.g. in the body) and be lost physically from the fiber so it can no longer do its job preventing oxidation. We will look at both of these independently to see whether there is enough antioxidant.

Hindered phenol consumption by preventing oxidation
If we ignore the physical loss of antioxidant into the water inside the body we can estimate the time it will take for the mesh to have used up all of the antioxidant. The defendants have used an article by Woo to estimate the shelf-life of Marlex, so we will use the same article[10]. Below is Figure 5 in the Woo article. The PP loses one minute of OIT per year of storage at room temperature. The Marlex® HGX-030-01 pellets were found to have an OIT of 6 minutes so they would be expected to have about 6 years of stability before all the antioxidant was used up. At that point, the PP is unstabilized, and as we know, that will lead to failure in a short time period.

The OIT of the Marlex® HGX-030-01 mesh is only 2 minutes because most of the antioxidant has been used up when the PP pellets were melted to make the fiber. An OIT of 2 minutes means an expected shelf-life at room temperature of 2 years. At that point, the PP is unstabilized and will oxidize, become brittle and break.

By this method, the Marlex® HGX-030-01 has only enough antioxidant to protect it for 2 years at room temperature. It would be expected to fail even faster in the body where the temperature is higher.

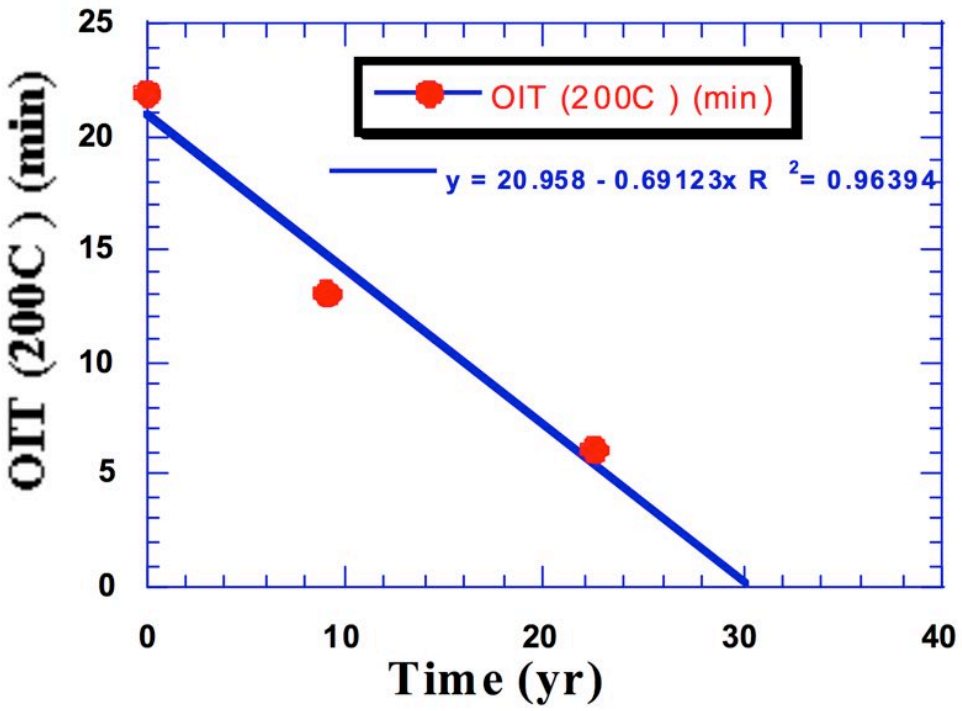


Figure 7 PP stored at room temperature loses ~1 minute of OIT for every year of storage[10]

Hindered phenol loss into the water phase

It is known that for thin PP items, physical loss of the antioxidant is more important, i.e. much faster, than chemical consumption. That is why manufactures use special extraction resistant antioxidants for such items (e.g. geomembranes). Boston Scientific did not use the correct type of extraction resistant antioxidant. The article that Boston Scientific have used internally to evaluate the stability of PP fibers is called "Antioxidant depletion and oit values of high impact PP strands"[11]. The article showed that hindered phenol was extracted by water in a relatively short time whereas the polymeric hindered amine type was not. We can be sure that the loss of antioxidant will be a major factor in leaving the PP unprotected and prone to failure by oxidation. They found that degradation occurred much more rapidly in water than in air at the same temperature (Figure 8).

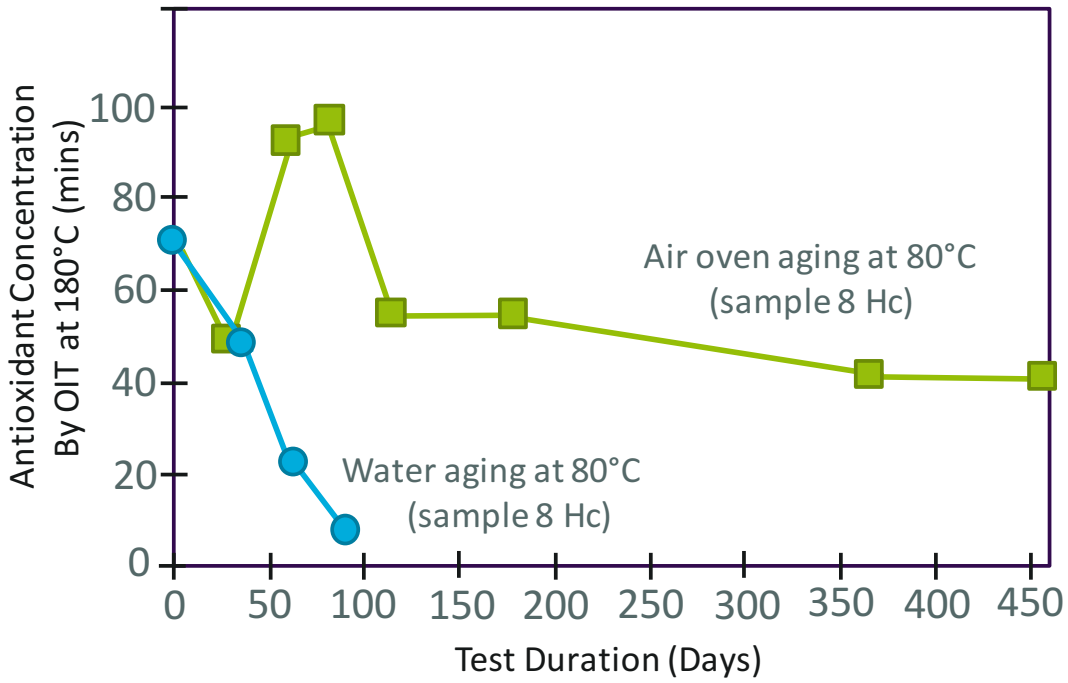


Figure 8 Oxidation of PP fibers in water is much faster than in air due to antioxidant loss into the water[11]

The studies were performed at 80 and 90°C, which is relatively near to the body temperature and expected to give meaningful results. The samples tested were commercial PP fibers and tellingly, they all contained 4000ppm of antioxidant or more. This shows that properly stabilized PP fibers on the market contain vastly more stabilizer than Marlex® HGX-030-01. The reason is that the Marlex contains only a basic stabilization package. The manufacturer of the final product is supposed to add more antioxidant to ensure the PP resin can survive in its end use.

There are other articles showing similar results. A very detailed study on geomembranes was published recently[12]. They looked at 29 different polyolefin-based products (geo- membranes, geonets, and geotextiles), many of them were polypropylene. These studies are highly relevant because they were on commercial products with various stabilization packages. They noted that, as expected, the products oxidized more quickly when exposed to water than when aged in air at the same temperature, 80°C. The conclusions for products stabilized with the same type of antioxidant (AO) used in Marlex® HGX-030-01 are as follows.

"All products, which were stabilized by a combination of phenols and phosphites or sulfides (AO packages of type P1), showed no degradation of the tensile properties as long as AO were present (indicated by non-zero OIT value). AO depletion proceeded faster in water than in air. After depletion of the AO, the tensile strength and elongation at break were rapidly impaired by oxidation."

They also looked at some PP stabilized with higher molecular weight hindered amine (HAS) stabilizers in addition to the hindered phenol. They stated the following.

"No depletion of HAS-3 and HAS-11 was observed in the immersion tests."

This is important. Just as in the previous study, it was found the high molecular weight HAS are most effective for thin PP items immersed in water because that kind of stabilizer is resistant to extraction. It stays in the PP and protects it.

They noted that a combination of hindered phenol and HAS is the best solution. That is just what was proposed in my previous report as a promising solution for PP mesh. They phrased it in this way.

"After depletion of these AO, the possibly still present HAS will prevent catastrophic failure by slowing down the degradation. Such a "coaction" may especially work in aqueous or moistly environments, where certain high- molecular HAS will deplete less rapidly than phenols and therefore may prevent "catastrophic" failure."

It is clear that the stabilization used in Marlex® HGX-030-01 is not close to being sufficient and that much more effective options were known but not employed.

Summary

Boston Scientific have failed to provide evidence that the PP mesh is stable inside the body. In fact, they have admitted that they did no testing whatsoever to evaluate whether the PP would survive when implanted (Rao deposition). It is remarkable that they realized that antioxidant is consumed over time and that it can be extracted and yet they did no testing at all to ensure the safety of their product. They purchased a polypropylene grade specifically forbidden from use in permanent implants by the manufacturer (clearly stated on the safety datasheet) and used it anyway without adding any stabilizer to protect it.

When a consumer buys a car for example, a large part of the price is the extensive R&D, design and safety testing. We pay a premium for brands that are known to provide better quality. In the case of the PP mesh, the raw material costs about $1/lb and the mesh sells for around $100,000/lb. One would assume that the gigantic premium is due to all the extensive testing and special stabilization package. However, it turns out that Boston Scientific chose to not bother to do the durability testing. Having worked at major corporations like Electrolux (Frigidaire) and BASF, I can tell you that responsible companies pay enormous attention to the durability of their plastics and selection of suitable stabilizer systems. Hundreds or even thousands of hours of durability testing are performed by responsible companies.

China Sourced PP cannot be Genuine Marlex® HGX-030-01

The other main point from previous reports was that the China sourced PP that Boston Scientific is presently selling for implantation in women is not genuine Marlex® HGX-030-01 and therefore not FDA approved. The defendant's experts try to make the point that the China sourced PP is similar to the genuine Marlex® HGX-030-01 but that is not good enough. Only the genuine product was approved, not something merely similar. It is extremely easy to prove that the China sourced PP is not Marlex® HGX-030-01. In Table 2 we compare the formulations of Marlex® HGX-030-01 dating back from 1993 to the present[13].

Date	Acid Scavenger	Phosphite	Hindered Phenol	Same as China Sourced PP?
[redacted]				NO
				NO
				NO
				NO
				NO
				NO

Table 2 Formulations of Genuine Marlex HGX-030-01 provided by Chevron under protective order

Marlex® is a registered trademark of Chevron Phillips Chemical Company LP. That means that it is illegal to use the Marlex tradename for PP that is not genuine Marlex. And yet, Boston Scientific have written to the FDA stating that they are still using genuine Marlex® PP.

A polypropylene is only genuine Marlex® HGX-030-01 when it is made by Chevron according to Chevron's formulation. The China sourced PP resin recipe does not match any formulation ever used by Chevron for Marlex® HGX-030-01. Therefore, the China sourced PP is, by definition, **not Marlex®***. No other conclusion is possible.*

Explanation of Table 1 and why the Chinese PP cannot be Marlex® HGX-030-01

This section explains exactly how China sourced PP used now is different from each of the Marlex® HGX-030-01 formulations used.

The China sourced PP is not the same as Marlex® HGX-030-01 made before [redacted] because:

1. *The China sourced PP does not contain [redacted]*
2. *It contains no [redacted]*
3. *It contains too little [redacted]*

The China sourced PP is not the same as Marlex® HGX-030-01 made from [redacted] because:

1. *The China sourced PP does not contain [redacted]*
2. *It contains too little [redacted]*
3. *It does not contain [redacted]*

The China sourced PP is not the same as Marlex® HGX-030-01 made from [redacted] because:

1. *China sourced PP does not contain calcium stearate*
2. *It contains too little [redacted]*
3. *It does not contain [redacted]*

The China sourced PP is not the same as Marlex® HGX-030-01 made from [redacted] because:

1. *The China sourced PP does not contain [redacted]*
2. *It contains too little [redacted]*
3. *It does not contain [redacted]*

The China sourced PP is not the same as Marlex® HGX-030-01 made from [redacted] because:

1. *The China sourced PP does not contain [redacted]*
2. *It contains too little [redacted]*
3. *It does not contain [redacted]*

The China sourced PP is not the same as Marlex® HGX-030-01 made from [redacted] *the present day because:*

1. *The China sourced PP does not* [redacted]
2. *It contains too little* [redacted]
3. *It does not contain* [redacted]

Boston Scientific are using a counterfeit PP which they bought from a distributor who they knew to be a counterfeiter. Their own colleagues sent an email warning them not to buy from EMAI because they were selling counterfeit polymer. The China sourced PP from EMAIl contains contaminants not found in genuine Marlex (as detailed in my previous report). The China sourced PP also contains a different stabilizer called Irganox® 1330. Here is what the safety datasheet for Irganox® 1330 says:

BASF
We create chemistry

Safety Data Sheet
Irganox® 1330

Revision date : 2017/01/26 Page: 1/11
Version: 4.0 (30475161/SDS_GEN_US/EN)

1. Identification

Product identifier used on the label

Irganox® 1330

Recommended use of the chemical and restriction on use
Unsuitable for use: This material is not intended for use in products for which prolonged contact with mucous membranes, body fluids or abraded skin, or implantation within the human body, is specifically intended, unless the finished product has been tested in accordance with nationally and internationally applicable safety testing requirements. Because of the wide
range of such potential uses, we are not able to recommend this material as safe and effective for such uses and assume no liability for such uses.
Recommended use*: antioxidant; stabilizer

This would indicate that Boston Scientific would have to requalify the mesh according to "internationally applicable safety testing requirements" due to the change in antioxidant from Irganox® 3114 used in genuine Marlex® HGX-030-01 to the Irganox® 1330 used in the China sourced PP resin.

Rebuttal of Boston Scientific's Expert Reports

Comments on Exhibit H - Dr. Steven Little

Dr. Little states: "Polypropylene has a proven, long-history of safe use in the human body, including as a permanent, implantable mesh for the repair of soft tissue defects."

Polypropylene does indeed have a long history of use but that cannot be characterized as safe because the polypropylene mesh and sutures have been shown to degrade in the body. Tens of thousands of hernia and pelvic mesh patients have experienced discomfort, pain and other symptoms so serious that many underwent operations to remove the mesh. Dr. Little's statement does not jibe with the facts.

Dr. Little states: "Foreign Body Response to Polypropylene Mesh is Expected and Necessary."

It is not true that a foreign body response is necessary. Truly biocompatible polymers are known and they elicit no foreign body response[14]. In contrast, polypropylene causes a prolonged biological response leading to inflammation and eventual encapsulation of the PP mesh in fibrous scar tissue. This is not necessary and in fact, much effort has been put into developing biocompatible polymers or developing biocompatible coatings for PP to reduce or eliminate this foreign body response[15]. Cheng et al, reported that coating the PP resulted in "less corrosion of the polypropylene" and a "milder chronic inflammation response"[16]. In fact, Boston Scientific themselves have made collagen based repair material to overcome the serious drawbacks of synthetic PP mesh. Here is a quote from Boston Scientific's own Xenform Patient Brochure[17].

Q "What are the advantages of collagen grafts as opposed to synthetic meshes?

A "While synthetic meshes have been used for decades for pelvic floor reconstruction, they have been associated with an increased risk of infection and erosion of the material into the lower urinary tract or vagina, which can result in voiding difficulty or sexual complications."

"Collagen grafts, however, are designed to mimic the body's natural tissues. These scaffolds possess biologic properties that encourage cell and blood vessel

penetration, allowing for remodeling of the graft into new tissue, providing natural, more lasting repair of soft tissue defects."

Dr. Little's statement is not true according to his client, Boston Scientific. The scientific literature also shows that PP causes adhesions and tissue reaction such that the fiber needs to be coated to prevent those problems[18].

the possibility of transmitting infectious BSE (Bovine Spongiform Encephalopathy, or "Mad Cow Disease").

[1] Data on file, TEI Biosciences Inc.

Boston Scientific

Delivering what's next.™

Xenform Soft Tissue Repair Matrix is manufactured by TEI Biosciences Inc. and distributed by Boston Scientific.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com/gynecology

Ordering Information
1.888.272.1001

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MVU5790 10M 4/06-4/08

What is The Xenform™ Matrix?

A: Xenform Soft Tissue Repair Matrix is a natural, collagen mesh designed to repair damaged or weakened soft tissues.

How is it made?

A: The Xenform Matrix is derived from the skins of fetal calves – one of the purest sources of collagen available. The skins are thoroughly cleaned and treated to remove cellular components as well as viruses present in the tissue. They are then sorted by thickness, freeze-dried, cut into convenient sizes and sterilized.

What are the advantages of collagen grafts as opposed to synthetic meshes?

A: While synthetic meshes have been used for decades for pelvic floor reconstruction, they have been associated with an increased risk of infection and erosion of the material into the lower urinary tract or vagina, which can result in voiding difficulty or sexual complications.

Collagen grafts, however, are designed to mimic the body's natural tissues. These scaffolds possess biologic properties that encourage cell and blood vessel penetration, allowing for remodeling of the graft into new tissue, providing natural, more lasting repair of soft tissue defects.

What other types of collagen grafts are available?

Collagen grafts are sometimes harvested from elsewhere on the patient's own body. Of course this is advantageous in terms of biologic acceptance of the autologous tissue; however, it may increase surgery and recovery time, predispose patients to incisional hernias, and leave undesirable cosmetic results.

Another approach is to use allograft tissue from human cadavers. These tissues are screened for viruses, treated with antibiotic solutions, freeze-dried and sterilized. While human allograft tissues have been shown to be effective for many applications, there are supply limitations, and the mechanical strength of the tissue can vary substantially from donor to donor, potentially leaving the patient at a higher risk of surgical failure of the graft.

To help overcome the limitations described above, clinicians have turned to xenograft materials (those derived from animal tissues) to satisfy their soft tissue repair needs. Not only is the source material

Dr. Little states: "While polypropylene, especially unstabilized polypropylene, can indeed undergo oxidative degradation at high temperatures (thermo-oxidation) and under ultraviolet light, the conditions in the human body would not lead to material degradation of the polypropylene mesh. Simply put, studies of thermal oxidation of polypropylene cannot be extended to the human body."

Firstly, it should be mentioned that Dr. Little is not a polymer scientist and is therefore not qualified (according to his resume) to render an expert opinion on

polymer science topics. Secondly, his statement is demonstrably incorrect. It has been shown over and over again that polypropylene is unstable even at room temperature, i.e. well below body temperature. Boston Scientific are aware that the PP is attacked even at room temperature, for example their internal memos show they were trying to calculate the shelf-life of the PP pellets. I.e. they wanted to know how long it would take for the PP to degrade on the shelf at room temperature. Indeed, the article they cited, by Woo et al.[10], showed that the stabilizer is consumed even at room temperature. Boston Scientifics expert Dr. Sean Curran conceded the same point in his deposition. Dr. Little is not correct that PP is stable at room temperature. Neither the scientific literature nor his own client support his view.

It has further been shown that PP can be attacked by biological systems. Lastly, it has been known for decades that PP degrades rapidly in the body due to oxidation and loses its mechanical strength[21].

Dr. Little states: "The Marlex HGX-030-01 polypropylene resin that was used in Boston Scientific's Advantage and Polyform meshes contains a primary antioxidant (Irganox 3114), a secondary antioxidant (Irgafos 168), and a stabilizer (DHT-4A). The presence of primary and secondary antioxidants further prevents oxidation and chemical degradation of the polymer in vivo."

He is correct that genuine Marlex HGX-030-01 contains those stabilizers mentioned. However, Dr. Little is incorrect in saying that the primary and secondary antioxidants protect the PP in vivo. It is well known that secondary antioxidants provide no long-term stability whatsoever. Dr. Little once again shows his lack of understanding about polymers and stabilizers for polymers.

Nevertheless, for both PP materials, it has been conclusively demonstrated in my expert report that the amount of antioxidant in the mesh is too low i.e. the mesh would need to contain at least 20x more hindered phenol to have any chance of surviving for the required time in the body. Even that would probably not be sufficient.

Dr. Little claims there is no strong evidence that PP degrades in vivo but he does not support that with any valid articles to back the claim. In contrast, my own expert report (and this report) provides many references demonstrating that PP degrades rapidly in air at room temperature. It also shows that PP degrades very

rapidly in water because the stabilizer is washed out of the PP and is no longer present to protect the polymer. The DeArmitt expert report shows that PP is readily attacked by microbes at room temperature and that it degrades in vivo.

Dr. Little says: "Notably, it is clear from the evidence in the literature that upon cleaning of the explanted samples, the polypropylene mesh's appearance is unchanged from a pristine sample of polypropylene mesh."

He cites an article by Thames et al. to support his point[19]. However, the Thames article is not applicable to this case for three reasons. Firstly, Thames used a unique cleaning method that has not been validated by others. There is an article dedicated to refuting the Thames work[20]. Secondly, the work was funded by Ethicon so there was a clear conflict of interest. Thirdly, and perhaps more importantly, Thames specifically states that his work applies only to Ethicon mesh and his conclusions only apply to that mesh because it contains different amounts and types of stabilizers compared to other mesh products. Indeed, Thames is correct to warn against applying his findings to other mesh. Ethicon mesh contains between 20-40x more long-term stabilizer than Boston Scientific PP mesh. Thus, even if that highly stabilized Ethicon mesh resists oxidation, that proves nothing about the stability of Boston Scientific's mesh, which barely contains any stabilizer.

Dr. Little cites the well-known Liebert paper[21] which showed that unstabilized PP began to oxidize rapidly about 60 days after implantation as measured by FTIR spectroscopy. Liebert also showed that stabilizer prevented oxidation, at least for the short duration of his experiment (160 days).

Dr. Little states: "Moreover, for the unstabilized polypropylene filaments, any changes in mechanical properties were only observed at the beginning of implantation (first 30 days, when any observed surface detection of [OH] chemical groups were the weakest), and importantly, no change in mechanical properties was detected whatsoever during the period of most rapid increase in [OH] group that was allegedly caused by oxidation ("hydroxyl group presence increase occurred between 50 and 90 days of implantation when there was no change in physical properties")".

The results that Dr. Little comments on are completely as expected. Dr. Little is not a polymer scientist and presumably does not realize that rapid oxidation, as detected by FTIR, occurs after mechanical properties have already changed.

Dr. Little opines that the cracked appearance of explanted PP fibers is due to adsorbed biological material. He believes that the adsorbed material causes the peaks in the FTIR spectrum that have been attributed to oxidation by other workers. However, detailed studies have categorically proven that the surface of the PP fibers is indeed oxidized. For example, Imel et al. analyzed Boston Scientific Pinnacle mesh made from Marlex HGX-030-01 and showed that the PP lost molecular weight which causes a concomitant loss of mechanical properties[22]. Simply put, the polymer chains are broken by oxidation when implanted and become unable to support a load. Imel also used EDAX which is able to distinguish between oxidation of the PP and adsorbed biological material. They concluded:

"These findings demonstrate that we are able to locate clean fiber in this sample and that oxidation of these fibers has occurred even before horizontal cracks appear. We are able to use a combination of SEM imaging and EDS to clearly distinguish between PP-fiber and biological material."

They concluded by writing:

"Collectively these results, as well as the loss of flexibility and embrittlement of polypropylene upon implantation as reported by other workers, may only be explained by in vivo oxidative degradation of polypropylene."

Other workers have confirmed that the cracked layer on the PP fibers is oxidized PP and not biological material[23]. The cracked PP layer is visible in polarized light whereas the adsorbed biological material is not. The oxidized PP can be stained because the oxidized areas provide sites for the stain to bind to the PP fiber, whereas the non-oxidized PP fiber core does not respond to staining. They listed several proofs that the cracked fiber surface is oxidized. Surface cracks severely weaken the fiber in the same way that notching a tree truck makes it much easier to fell.

Dr. Little appears to be unaware of these more recent works proving unambiguously that the surface of PP fibers is oxidized and cracked in vivo[23].

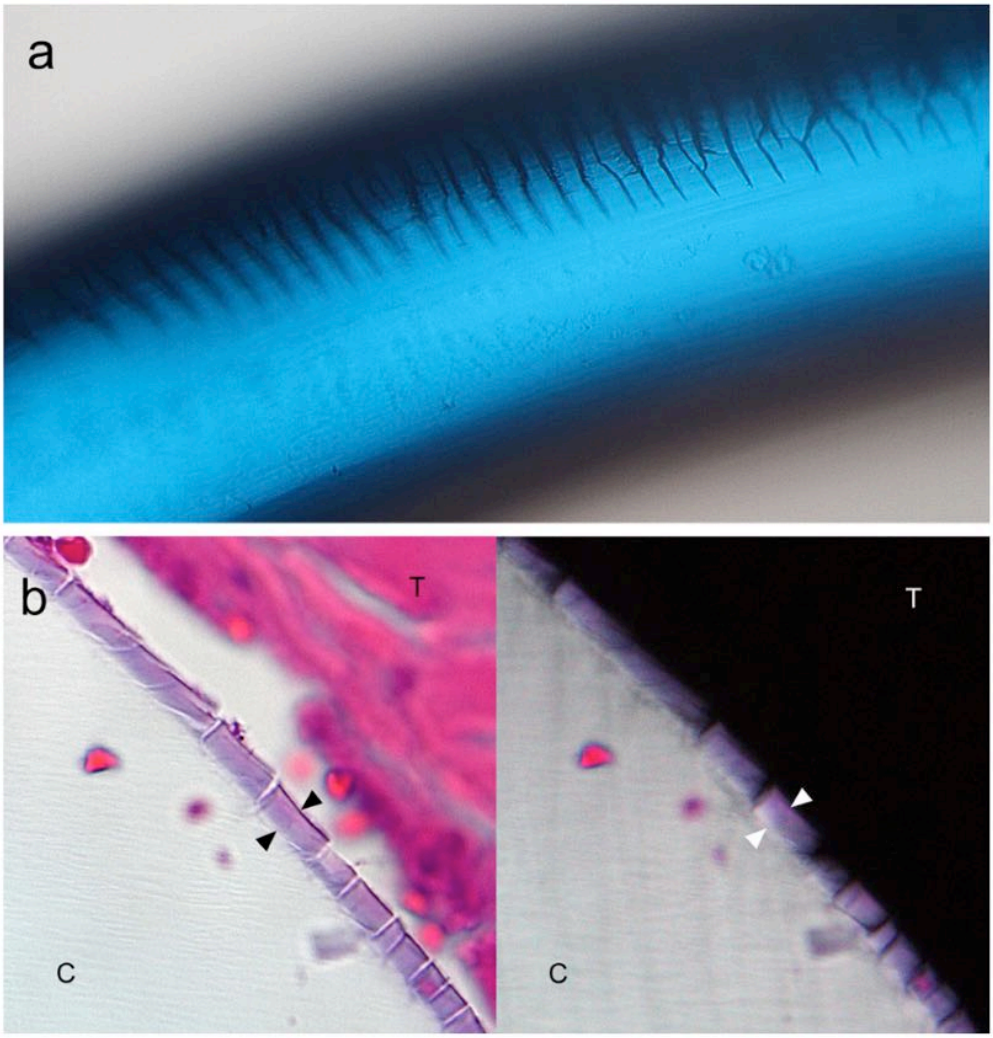


Fig. 1 Fibers of explanted vaginal mesh. **a** A blue mesh fiber of a TVT® sling photographed immediately after removal from the body, before exposure to formalin. Photographed using conventional light microscopy, magnification approximately ×600. **b** Histological section of an explanted Ethicon transvaginal mesh device (clear fiber), stained by hematoxylin and eosin (H&E) stain, magnification approximately ×1,000. The cracked surface layer absorbs histological dyes (*between arrowheads*) whereas the nondegraded core (*C*) remains clear (*left*). On the *right*, the same field is photographed in polarized light. The degraded layer (*between arrowheads* and polypropylene core, *C*) polarize; the tissue composed of protein (*T*) does not

Figure 9 Excerpt from Iakovlev et al.[23] showing staining of a cracked oxidized layer around a PP fiber

Dr. Little claims he knows of no biodgradable PP. As we have already shown, unstabilized PP is readily biodegraded in a landfill, by microorganisms or inside the body.

Biodegradation of PP is well-proven and such products are on the market i.e. EcoPure® from BIO-TEC
http://www.goecopure.com/biodegradable-polypropylene-plastic.aspx

"American Profol cast polypropylene films containing EcoPure™ additive have been shown to biodegrade under ASTM D5511-02 (Standard test method for determining anaerobic biodegradation of plastic materials under high-solids anaerobic-digestion conditions)*. These conditions are designed to simulate anaerobic landfill conditions."
http://www.profol.com/en/cpp-products/biodegradable/biodegradable.html

Metal stearates have proven efficacious in bringing about accelerated degradation of PP[5]. Another article on degradable PP is Effects of Manganese Stearate on Stabilization Efficiency of Phenolic Antioxidants in Polypropylene[24].

Another source of an additive to give degradable PP is here:
http://www.symphonyenvironmental.com/d2w/

This information was found in a few seconds by doing a Google search for "biodegradable polypropylene".

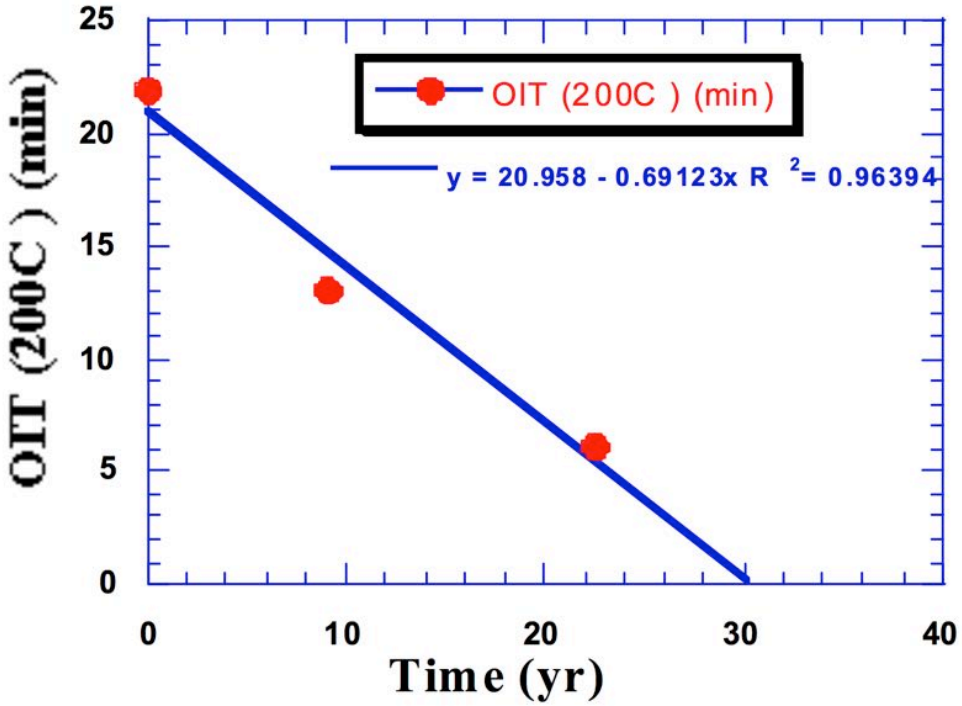
Clearly, unstabilized PP is biodegradable and other biodegradable PP products are on the market. A Google search for "biodegradable PP" is all that is needed to illustrate the point.

Comments on Exhibit L - Dr. Charles A. Daniels

I will address Dr. Daniels opinions in the same order in which he stated them in his report.

1. I agree that polypropylene is a versatile polymer suitable for a wide range of applications. He goes on to state that "Polypropylene can be stabilized against degradation with a variety of additives to ensure that it maintains its physical properties for an appropriate life span in its end use environment." Polypropylene can be stabilized but it is not at all certain that the stabilization will protect it for the intended lifespan of the product. Many instances exist where PP failed due to improper stabilization.
2. I agree that all analyses to date have shown antioxidant in the PP pellets and the final mesh. That was never disputed. We showed, based on a wide variety of methods, that the amount of stabilizer in the mesh is woefully short of the amount needed and the type of stabilizers are not suitable for long term use in contact with water e.g. in body fluids.
3. We agree that FTIR does not show oxidation of the mesh before implantation. Nor would one expect to see oxidation of the fiber new in the box. What we have shown and what has been reported widely in the literature, is that explanted PP mesh is oxidized and degraded. This has been shown beyond doubt.
4. They claim that the mesh meets all performance criteria. Firstly, we noted that when they performed OIT measurement and the PP failed their test, Boston Scientific's answer was to change their test criterion from within 20% to within 75% match between genuine Marlex and China sourced PP. It is meaningless for a company to claim they passed their tests when they actually failed. We also note that they did not test "in accordance with generally recognized standards". For example, they did not follow ASTM D 3895 for OIT. The expert claims that samples "do not undergo oxidative degradation under normal storage conditions at the rate suggested by Plaintiffs' retained witnesses ". We did not claim that the PP is oxidizing significantly during storage. Instead we proved that the antioxidant is being consumed during storage and that was supported by Sean Curran in his deposition. In my initial expert report, I showed this graph from an article that workers at Boston Scientific had used to calculate the shelf-life of their PP pellets. That graph (below) is clearly shows that the antioxidant is being consumed during storage of the PP at room temperature. Boston Scientific's PP mesh has an OIT of between 2 and 3 minutes at 200°C

(based on triplicate measurements on three meshes made using China sourced PP). According to the Woo article[10] Boston Scientific used to estimate shelf-life we can predict that the mesh would survive 2-3 years at room temperature before the antioxidant was all used up. At that point, the PP becomes unstabilized and we have shown that unstabilized PP only survives for 1000 hours or less before it fails mechanically. Dr. Daniels is therefore not correct when he states that the PP is not affected by storage. The thin mesh fibers will fail even earlier due to their high surface area.



From Polypropylene Degradation and Durability Estimates Based on the Master Curve Concept, Woo 2001

5. Dr. Daniels says that my report used "scientifically unsound comparisons to the stabilizer additive packages found in another manufacturer's surgical mesh devices and stabilizer additive packages found in different commercial products altogether". We applied several independent methods which each showed that the PP mesh is drastically under-stabilized. In fact, Boston Scientific's own documents agree with that point. They predict a shelf life for their PP of 20 years or more when the PP mesh has to survive much longer than that, i.e. for the lifetime of the patient which means over 60 years. How can the expert disagree with us when his

own client agrees? Dr. Daniels does not agree that comparison of the stabilization of other PP products is relevant. Surely it would be unwise to discard what we have learned over the last 50 years about stabilization of PP in deciding whether the mesh is appropriately stabilized.

6. He noted that plaintiff's experts recommended using a HALS stabilizer without proving it would work and that it was safe. The reason that we recommended that type of stabilizer is that it is the only kind known to work for thin PP parts that are exposed to water and need to survive for many years. For example, the article entitled "Antioxidant depletion and OIT values of high impact PP strands" which the defendants circulated internally at Boston Scientific, shows that all PP fibers stabilized with hindered phenols and exposed to warm water suffered from rapid antioxidant loss by extraction in to the water. For example, 100% of the Irganox 1330 was lost in 800 days at 90°C. In contrast only 24% of the HALS (Chimassorb 944) was lost in 800 days at 90°C. We know from this and other publications that hindered phenols are extracted by the water leaving the PP unprotected. The HALS is a much larger molecule and remains inside the PP where it can do its job as a stabilizer. We recommended the high molecular weight HALS because it is the only known class of commercial stabilizer known to be effective for protecting thin PP parts exposed to water for periods of years or decades. In regard to safety, the HALS is not expected to interact with the body because it stays inside the PP. In contrast, the hindered phenols that Boston Scientific use are known to migrate out of the PP and into the water phase. We did not recommend the HALS stabilizer because it is certain to work, we recommended it because the data shows that the hindered phenols used now are certain to fail. Dr. Daniels claims he has seen no evidence that HALS are biocompatible and yet a Google search for "hindered amine biocompatible" gives hits where the third hit on the first page is an article showing that a HALS derivatized polymer is biocompatible[25].

Dr. Daniels quotes from the high impact PP strands paper saying they found "no oxidative degradation" had taken place.

The actual quote reads "…no significant oxidative degradation has taken place in the stabilized bulk material during oven aging and water immersion." The article specifies that oxidation did not take place in the bulk, i.e. inside the fiber, because they did find oxidized species on the fiber surface using ATR-

FTIR spectroscopy. Dr. Daniels neglected to mention that important finding. Those oxidized species were removed by brushing and washing in solvent whereupon the workers made the conclusion that "…no significant oxidative degradation has taken place in the stabilized bulk material during oven aging and water immersion."

Dr. Daniels goes on to say "In fact, Müller, et al. found that "no significant oxidation degradation" had taken place in polypropylene fibers that had been immersed in water at 90°C – a highly oxidative environment – for more than two years after their antioxidants had been depleted and their OIT values had reached zero."

The statement is untrue. The article does report carbonyl peak formation and oxidation as measured by ATR-FTIR. Furthermore, the FTIR was done on a PP fiber stabilized with a combination of hindered phenol Irganox 1330 plus Chimassorb 944 where the latter is not present in Boston Scientific resin. The fibers contained far more stabilizer and a far better stabilization package than Boston Scientifics PP products. Furthermore, the sample he refers to still contained antioxidant. Lastly, they evaluated brittleness using a compression test, which is insensitive. Usually, one measures elongation to break instead.

Dr. Daniels wrote "Mowery, et al. found that it took more than 100 days at 100°C for even unstabilized polypropylene powder to begin to show signs of oxidation, and that the polypropylene had undergone only relatively minor oxidation after 250 days at 100°C". I checked the Mowery paper he cited[26] and it did not contain the information stated by Dr. Daniels.

What the Mowery article actually shows, is that the unstabilized PP oxidized in just 40 hours, not the "more than 100 days" that Dr. Daniels claimed. He was also wrong about the test temperature, as no work done on PP at 100°C. Mowery performed at ageing of PP at 108°C and that is shown below (Figure 10). The diagram below is taken from Figure 7 in the Mowery article on page 5042.

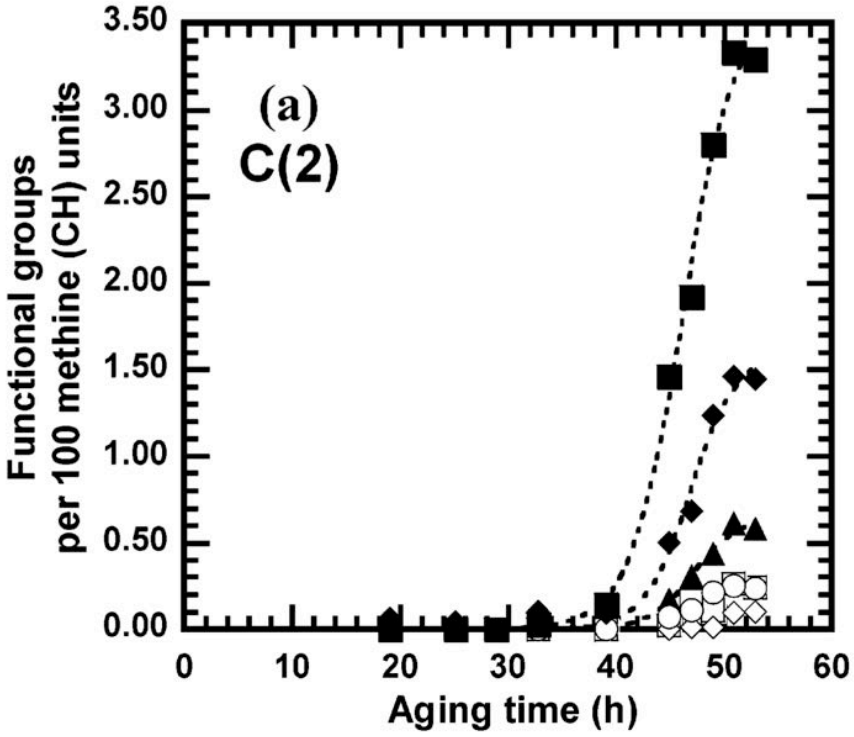


Figure 10 Rapid oxidation of unstabilized PP after 40 hours at 108°C after Mowery et al.[26]

I looked at the Mowery article to see where Dr. Daniels got the "over 100 days" of stability claim from. On page 5041 of the Mowery article does show over 100 days of stability for unstabilized PP but not at 100°C, instead that ageing was done at just 50°C. The original data, which is figure 5 in the Mowery article is shown below (Figure 11).

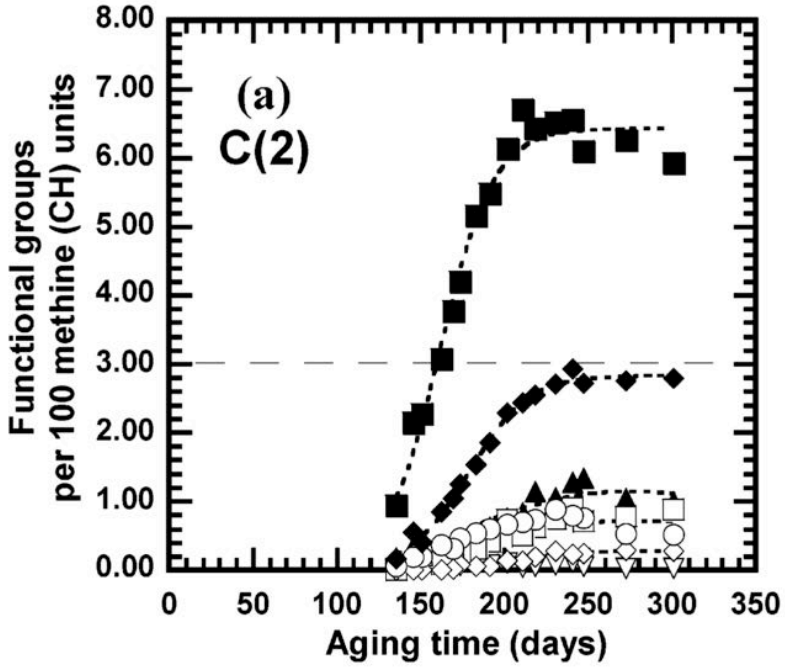


Figure 11 Oxidation of unstabilized PP after 100 days at 50°C after Mowery et al.[26]

Next Dr. Daniels writes "That is consistent with the finding by Hsuan, et al. that the oxidative "reaction rate at ambient temperature is so slow that the evaluation of oxidative degradation becomes impractical to simulate in the laboratory." In that article the author is talking about[27] this diagram (Figure 12) and he remarks that the oxidation of stabilized PP is too slow to measure conveniently at room temperature so it is common to accelerate the oxidation by raising the temperature.

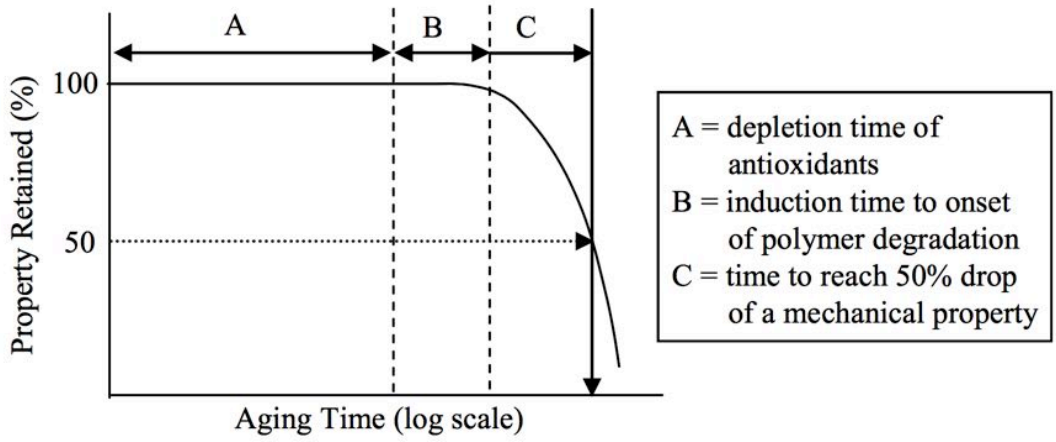


Figure 7. Three conceptual stages in oxidation of polyolefin geosynthetics

Figure 12 Depletion of antioxidant occurs before oxidation accelerates after Hsuan[27]

Hsuan's exact words were:

"To evaluate the oxidation of polyolefin in the laboratory, it is necessary to accelerate the rate of reactions so that the oxidation can occur within a reasonable duration. Temperature acceleration is the most common method."

Hsuan's comments do not support Dr. Daniel's argument. It is common knowledge that stabilized PP needs to be heated to accelerate the test, as a matter of convenience.

The next sentence from Dr. Daniels says "Likewise, Müller, et al. reported that unstabilized polypropylene samples did not undergo significant oxidative degradation for more than two years after being immersed in water at 90°C".

That is not at all what the Müller article shows. Firstly, there is not a single mention of unstabilized PP anywhere in the article. Here is the table showing that all samples investigated contained very large amounts of Irganox® and Chimmassorb® type antioxidant.

Table 2. Antioxidants and antioxidant concentrations found in the designated samples using analytical methods

Sample designation	Antioxidant and antioxidant concentration (% by weight)				
	Irgafos 168	Irgafos 168 phosphate	Irganox 1010	Irganox 1330	Chimassorb 944
Aa	0.03	0.03	0.03	–	–
Ba	0.05	–	0.04	0.39	–
Cb	0.04	0.03	0.03	0.51	–
Da	0.05	–	0.04	–	0.19
Ea	0.06	–	0.04	0.16	0.06
Fa	0.06	–	0.04	0.15	0.06
Gc	0.03	0.03	0.03	–	0.50
Hc	0.05	0.02	0.05	–	0.35

Figure 13 The PP samples investigated by Müller where all contain large amounts of stabilizer

Müller does indeed say "Yet, a significant brittleness of the random arrays of PP strands Ba, Da, Ea and Fa was not observable, even after 1150 days of immersion in 90°C hot de-ionized water!"

However, the samples mentioned all contain over 4000ppm of antioxidant so they are certainly not unstabilized as Dr. Daniels had stated. For comparison, Boston Scientific mesh contains a mere 200ppm of antioxidant. The only sample in the Müller article with a similar stabilizer level to Boston Scientific mesh was sample Aa (Figure 13) and Müller avoids mentioning the stability of that sample.

Dr. Daniels says "I would not necessarily expect a HALS to provide enhanced protection against degradation caused by exposure to moisture because the solubility in water of Chimassorb 944, the HALS suggested by Plaintiffs' retained witnesses, is nearly the same as the primary antioxidant (Irganox 3114) used in one formula of Marlex HGX-030-01.". His statements are nonsensical because on page 440, Table 3 shows that it takes about 300 days for half of the Irganox 1330 to be lost in water at 80°C and on the same page Table 4 shows that it takes 2000 hours for half of the Chimassorb 944 to be lost under the same conditions. The data in the article Dr. Daniels cites show exactly the opposite of what Dr. Daniels claims.

His remark that Chimassorb 944 is almost the same as Irganox 3114 shows a remarkable lack of chemical knowledge. The figure below shows the two molecules and even a layperson can see that they are not at all similar.

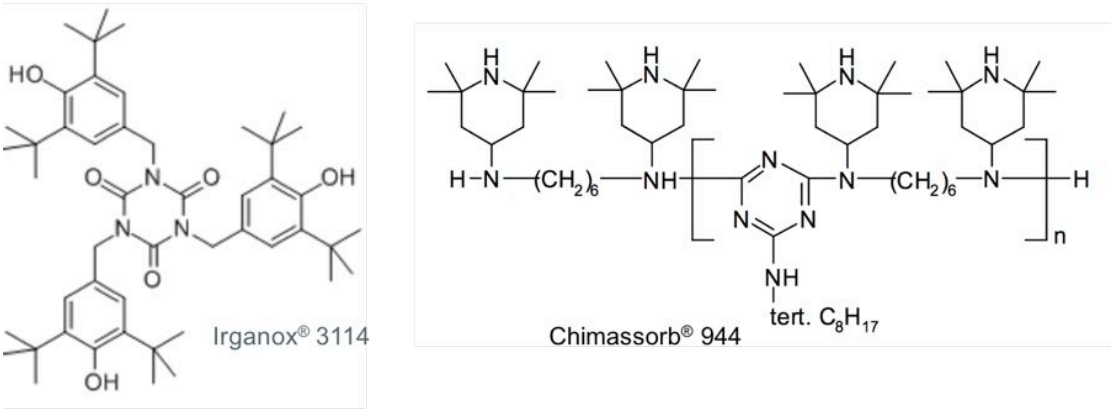


Figure 14 The chemical structures of Irganox® 3114 and Chimassorb® 944 are not at all similar

Dr. Daniels consistently misrepresents the findings in the scientific articles he cites.

The next statement is "Plaintiffs' retained witnesses' methodologically flawed analysis also rests on the erroneous assumption that Boston Scientific surgical mesh devices will catastrophically fail if and when their antioxidant levels reach zero."

Again, Dr. Daniels is incorrect. We have provided many references showing that unstabilized PP has very low resistance to oxidation and will fail. After all, a PP which has lost all of its antioxidant is then unstabilized.

Comments on the Expert Report of Dr. Stephen Spiegelberg Exhibit F

On page 6 Dr. Spiegelberg cites a study showing that polypropylene sutures retain their strength when exposed to simulated biological fluids at a range of pHs. That is expected because PP is resistant to water and because the study was only 12 weeks long. A proper stability test would be to expose the fibers to an oxidizing environment and for a longer period. Such studies have been done. Workers exposed the PP to oxidizing conditions as found in the body and found significant oxidation in a short period of time[33].

Dr. Spiegelberg correctly states that Marlex® HGX-030-01 contains Irganox 3114. As we know, the China sourced PP does not contain that antioxidant because it is not genuine Marlex® HGX-030-01. Even Boston Scientific's expert concedes that the China sourced PP contains the wrong antioxidant (see excerpt from his expert report, page 11).

> Marlex HGX-030-01 polypropylene resin contains three additives: Irganox 3114, Irgafos 168, and DHT-4A. Irganox and Irgafos are common, well-known antioxidants used in the manufacture of polymers, such as the polypropylene utilized in monofilament mesh.[39] Additionally, these specific antioxidants are on the recommended list for polypropylene for ophthalmic and parental drug containers according to the European Pharmacopoeia vs 5 (paragraph 3.16). Antioxidants are added to polypropylene resin to stabilize the resin during thermal processing (e.g. extrusion) and help ensure finished product durability in its application area. Irganox 3114 is a high extraction-resistant[40] primary antioxidant which acts as a free radical scavenger, therefore inhibiting oxidation from occurring. Irganox 3114 provides long-term protection to the polypropylene. Irgafos 168 is a secondary antioxidant, which act by converting hydroperoxides into stable species. Secondary antioxidants provide process stabilization by prevention of thermo-oxidation during polymer processing. The secondary

He says on page 12 that Ineos H03G-02 is a similar PP homopolymer and it contains no warning statement about implantation. In fact, the datasheet states

that the grade is not approved for food contact and they add a further disclaimer absolving them from any responsibility. That is why they did not have to add a specific sentence about implanting. They had already covered it under the following sentence.

"EOS Olefins & Polymers USA shall not be responsible for any damage or injury resulting from abnormal use, from any failure to follow appropriate practices, or from hazards inherent in the nature of the product and/or material, nor for toxicological effects or Industrial Hygiene associated with particular use of any product described herein."

I contacted Ineos and was told "…according to the datasheet, attached, this is a grade for tape, film and fiber and NOT a pharma grade."

On page 24 Dr. Spiegelberg claims that if crystallinity of PP does not change then the PP is not oxidized. This is simply untrue. Crystallinity often does increase when oxidation has become severe but his occurs long after the induction period[28] when the mechanical properties of the PP are already lost. Therefore, a PP can have lost its strength and function and still have no change in crystallinity. Some articles show a decrease in crystallinity when the PP is oxidized[29,30]. Crystallinity is not a good way, nor a common way, to track oxidation. It is an indirect and insensitive method. Much better ways are used such as detecting the oxidation itself by FTIR, EDS, SEM, iodometric titration or selective staining to name a few.

On page 24 he states that we claim that the mesh is being oxidized by the detanging process. We did not make that claim. In my report, I showed that every storage step and heating step consumes antioxidant so that less and less is left over to protect the mesh in the body.

On page 25 he opines that oxidation detected by FTIR and EDS could be due to biological residue. That is not true either. The workers used EDS to look for nitrogen which would be there if biological material was present. They found oxygen due to oxidation but no nitrogen or sodium and were able to conclusively rule out the presence of biological material and were therefore certain that oxidation had occurred[22].

At no point did we claim that the mesh is significantly oxidized before implantation. What we did show by repeated measurements was that most of the

antioxidant was consumed during storage and extrusion to create the mesh and that the very small amount remaining was not nearly sufficient to protect the mesh from oxidation in the body.

On page 41 of his report he claims that PP must be safe because any hazardous substances in it would have to be reported on the MSDS and none were. His argument is not valid. The MSDS does require reporting of hazardous substances but the hazard of using PP is in its mechanical failure due to oxidation. The Marlex MSDS does warn users to avoid exposing the PP to oxidants[31]. It is unfortunate that Boston Scientific chose not to heed that warning. As we know, the body response to a foreign object is to create a highly oxidizing environment.

Incompatibility (Materials to Avoid):	Oxidants
Hazardous Polymerization:	Will Not Occur
Conditions to Avoid:	Not Applicable
Hazardous Decomposition Products:	Carbon oxides and various hydrocarbon gases. Also, see Section F.

What Boston Scientific should have done is to expose the mesh to an oxidizing fluid such as found in the body. That study was performed and published by other workers and they found significant oxidation of the PP in just 5 weeks[32]. Another study on Ethicon mesh stated:

"The results demonstrated that over a relatively short time, a 6-month exposure, even a small concentration of ROS (1 mM) could decrease tensile strength of a sample of PP mesh by 31 %. Concentrations on this order have been known to occur physiologically in humans."[33]

They found rapid degradation of the PP mesh due to oxidation in just 6 months. One must bear in mind that was Ethicon mesh which has massively more (20x) stabilizer in it than Boston Scientific mesh. The Boston Scientific mesh would oxidize much sooner.

Comments on Exhibit J - Dr. James Rancourt

Dr. Rancourt's website gives a case study for one of his clients' including a video in which he describes in detail how he went about proving whether or not two polymer formulations were the same. He analyzed the two formulations and said:

"…I was able to determine that, the exact same chemicals, the exact same concentrations in fact were present in both formulations. So, as a result, it is my opinion that the two formulations were the same…"[34]

Dr. Rancourt is on record as saying that two polymer materials are identical if they contain the exact same chemicals at the exact same concentrations. The China sourced PP under discussion in this case contains neither the exact same chemicals, nor the exact same concentrations, as the genuine Marlex® HGX-030-01 he analyzed.

1. *The China sourced PP does not contain DHT-4A*
2. *It contains a much lower concentration of Irgafos® 168*
3. *It does not contain any Iragnox® 3114 but a completely different stabilizer*

I would be very interested to hear why Dr. Rancourt does not apply the same standards to the Boston Scientific mesh that he applies to his other work. According to Dr. Rancourt's own recorded methodology, China sourced PP cannot be genuine Marlex® HGX-030-01.

Comments on Burril Deposition April 27th 2017

Page 53 line 4 – he says that he knows unstabilized PP will oxidize readily at room temperature.

Page 65 line 3 – he says he knows that antioxidants can migrate out of the plastic.

Page 80 line 16 - he admits they knew that they found out from Chevron that the lot number on the China sourced PP bags was not a valid Chevron lot number.

Page 85 line 9 – he admits he wrote a report entitled "Marlex HGX-030-01 Equivalency Testing" saying the China sourced PP came in correct Phillips Sumika bags when at that time he did not believe that to be the case. He says he believed that the bags were those of a distributor. As I understand it, he knowingly misrepresented the facts.

Page 87 line 19 – he agrees that there is not a single thing lying the China sourced PP to Phillips Sumika.

Page 90 line 3 - repeats that they cannot trace the China sourced PP to Phillips Sumika.

Page 92 line 8 - he states that his report does not prove that the China sourced PP is genuine Marlex.

Page 92 line 21 - he will not answer whether his report claims China sourced PP is Marlex but instead replied "This report proves that it's equivalent to the Marlex."

Page 104 line 23 - he agrees that the one thing that distinguishes on plastic formulation from another is the proprietary combination of stabilizers.

That admission is very telling because all testing labs agree that the China sourced resin does not contain the same proprietary combination of stabilizers as genuine verified Marlex® HGX-030-01.

Page 116 line 5 - he says antioxidants are consumed over time even in storage conditions (line 12).

Page 176 - he admits they failed the OIT test within 20% and changed the test criteria to within 75%.

Conclusions

It is my opinion, as a polymer expert that the polypropylene mesh being used for implants is drastically under-stabilized for its intended use. Boston Scientific have admitted that antioxidants are consumed over time and can migrate out of the PP and yet they did no long-term testing, which indicates a blatant disregard for the safety of the patients.

I have read approximately 300 articles, patents, chapters, and other documents to be sure to grasp every aspect of this case and to render an accurate, unbiased opinion. From my experience, by conferring with other experts and based on that research, I am utterly convinced that the polypropylene is not even close to being properly stabilized *and furthermore that the China sourced PP is a) certainly not genuine Marlex® HGX-030-01 and b) is also under-stabilized for permanent implant use.*

As to the reports by Boston Scientific's experts, I am unswayed by their arguments for three reasons.

1. Many of the opinions are given without any support from the scientific literature (in contrast we provide a plethora of references)
2. The literature they do cite is either inapplicable to this case or studies that have been superseded by more detailed work disproving their point
3. Some of the claims made are patently false
4. They focus their attention on details which do not relate to the main points under discussion

Boston Scientific made no attempt to test whether their mesh would survive in the body even though they knew of the potential problems.

Recent Testimony – Chris DeArmitt PhD FRSC CChem

Deposition / trial testimony: None

Compensation

Dr. Chris DeArmitt FRSC CChem
An hourly rate of $250/hr applies to preparation, research and report writing.
Trial testimony, if applicable, is compensated at $400/hr.

Appendix A - Curriculum Vitae for Chris DeArmitt

Conference Chairing and Organizing

Polymer Degradation & Stabilisation Conference (Sweden 1999) – Organizer

Functional Fillers for Plastics, Intertech, (2002, 2007, 2008) – Chairman & Organizer

High Performance Plastics, RAPRA, Cologne (Germany 2011) – Organizer

Minerals in Compounding 2010, AMI, Atlanta Georgia (USA 2010, 2011, 2012) – Chairman / Organizer

Presentations

Conference in Mineral Processing (1999)
Macromolecules '99
Functional Fillers for Plastics (2000, 2002, 2003, 2004, 2005, 2007, 2008)
Nano-structured Materials (2002)
Engineering Thermoplastics (2004)
High Performance Fillers (2005*, 2006, 2007)
Cosmeceuticals Summit 2008
AddCon 2008
Nanopolymers (2008, 2009)
NPE/Antec (2009)
Advanced Materials Symposium (2009)
USM Business School (2009, 2010)
Smart Polymer Systems (2010)
Minerals in Compounding (2010, 2011**, 2012)
Plastics Modification: Additives, Compounding & Coatings (2011, 2012)
Silicone Elastomers 2011
Dragonite – SPE New Jersey Section 2011
Fire Retardants in Plastics 2012
InnoPlast Solutions 2012
BCC 2012
Polymer Foam 2012
Fire Retardants in Plastics 2014
Polymers in Cables 2014**
NPE/Antec (keynote) – USA (2015)
Plastics in Motion 2015
Compounding World Forum 2014*, 2016**

* Voted best presenter
** Voted best presentation and best presenter

Publications (excluding conference papers)

The Surface Characterization of Polyacrylonitrile-based Carbon Fibres by Electrochemical Techniques S. J. Porter, C. L. DeArmitt, R. Robinson, J. P. Kirby and D. C. Bott, High Perf. Polym., 1 (1), 85, (1989).

Synthesis of Novel Polyaniline Colloids Using Chemically Grafted Poly(N-vinylpyrrolidone)-Based Stabilizers C. DeArmitt and S. P. Armes, J. Colloid Interf. Sci., 150 (1), 134, (1992).

A novel N-substituted polyaniline derivative C. DeArmitt, S. P. Armes, J. Winter, F. A. Uribe, S. Gottesfeld and C. Mombourquette, Polymer, 34 (1), 158, (1993).

Colloidal Dispersions of Surfactant-Stabilized Polypyrrole Particles C. DeArmitt and S. P. Armes, Langmuir, 9, 652, (1993).

Surface Composition of Surfactant-stabilised Polypyrrole Colloids S. Y. Luk, W. Lineton, M. Keane, C. DeArmitt and S. P. Armes, J. Chem. Soc. Faraday Trans., 91 (5), 905, (1995).

A study of the kinetics of polymerization of aniline using proton NMR spectroscopy M. T. Gill, S. E. Chapman, C. L. DeArmitt, F. L. Baines, C. M. Dadswell, J. G. Stamper, G. A. Lawless, N. C. Billingham,S. P. Armes, Synthetic Metals, 93, 227, (1998).

Improving synthetic hindered phenol antioxidants; Learning a lesson from vitamin E K. D. Breese, J.-F. Lamèthe and C. DeArmitt, Polymer Degradation and Stability, 70, 89, (2000).

Filled polypropylene: a cost – performance comparison of common fillers C. DeArmitt & K. Breese, Plastics Additives & Compounding (Elsevier), 3, 9, 28-33 (2001).

Synthesis and evaluation of hyperbranched phenolic antioxidants of three different generations H. Bergenudd, P. Eriksson, C. DeArmitt, B. Stenberg, E. Malmström Jonsson, 76, 503-509, (2002).

Fillers & Surface Treatment C. DeArmitt & R. Rothon, Plastics Additives & Compounding (Elsevier), 4, 5, 12-14 (2002).

Thermoplastic Composites (Chapter 8) C. DeArmitt & M. Hancock, Particulate-Filled Polymer Composites, 2nd Edition, Editor Professor R. Rothon, RAPRA, UK, 2003.

Composites Using Nano-Fillers (Chapter 10) C. DeArmitt & R. Rothon, Particulate-Filled Polymer Composites, 2nd Edition, Editor Professor R. Rothon, RAPRA, UK, 2003.

Raising the softening point of PVC C. DeArmitt, Plastics Additives & Compounding (Elsevier), 6, 4, 32 (2004).

Styrene-based polymers offer diversity for processors C. DeArmitt, Modern Plastics, World Encyclopedia, 2004. (Revised & reprinted in 2005).

Thermoplastic compounds: finding the balance between performance and cost C. DeArmitt, Plastics Additives & Compounding (Elsevier), 7, 2, 26-29 (2005).

Fancy Fillers C. DeArmitt & R. Rothon, Plastics Additives & Compounding (Elsevier), 7, 4, 28-31 (2005).

Understanding filler interactions improves impact resistance C. DeArmitt Plastics Additives & Compounding (Elsevier), 8, 4, 34-39 (2006).

New thermo-opaque thermoplastics offer novel visual effects C. DeArmitt Plastics Additives & Compounding (Elsevier), 9, 6, 30-31 (2007).

POSS User's Guide C. DeArmitt POSS User's Guide 700 downloads per month since 2007.

POSS keeps high temperature plastics flowing C. DeArmitt & P. Wheeler, Plastics Additives & Compounding (Elsevier), 10, 4, 36-39 (2008).

Polyhedral Oligomericsilsequioxanes: Additives for Unique Cosmetic Properties C. DeArmitt Cosmetics & Toiletries (Allured Publishing), 123, 8, 51-56 (2008).

POSS Handbook C. DeArmitt (properties and applications of polyhedral oligomericsilsesquioxanes).

Innovation in Industry C. DeArmitt, SpecialChem Marketing and Innovation Newsletter #3, July 2009.

Filled with Success C. DeArmitt, Compounding World, July / August 2010.

The Open Approach to Open Innovation C. DeArmitt, European Plastics News, November 2010.

Polyhedral Oligomeric Silsequioxane (POSS) Enhanced Plastics (Chapter 23) C. DeArmitt, Functional Fillers for Plastics, 2nd Edition, Editor Professor M. Xanthos, Wiley-VCH, 2010.

Polyhedral Oligomeric Silsesquioxanes in Plastics (Chapter 5) C. DeArmitt, Applications of Polyhedral Oligomeric Silsesquioxanes, Editor C. Hartman-Thompson, Springer Press, 2011.

Functional Fillers for Plastics (Chapter 26) C. DeArmitt, Applied Plastics Engineering Handbook: Processing and Materials, Editor Myer Kutz, PDL, 2011.

Dispersants and Coupling Agents (Chapter 25) C. DeArmitt, R. N. Rothon, Applied Plastics Engineering Handbook: Processing and Materials, Editor Myer Kutz, PDL, 2011.

Making the Most of Minerals C. DeArmitt, Compounding World, February 2011.

Dragonite Handbook (the definitive guide to properties and applications of the nanotubular mineral halloysite) C. DeArmitt, 2012.

Magnetite (chapter) C. DeArmitt, Encyclopedia of Polymers and Composites, Springer 2014.

Particulate Fillers, Selection, and Use in Polymer Composites (chapter) C. DeArmitt and R. Rothon, Encyclopedia of Polymers and Composites, Springer 2014.

Surface Modifiers for Use with Particulate Fillers (chapter) C. DeArmitt, Encyclopedia of Polymers and Composites, Springer 2014.

Magnetite: exploring the multi-functional filler C. DeArmitt, Compounding World, August 2015.

Innovation Abyss: An Innovator's Solutions to Corporate Innovation Failure (book) C. DeArmitt, available on Amazon as paperback, hardback and Kindle versions.

Dispersants and Coupling Agents (Chapter 22) C. DeArmitt, R. N. Rothon, Applied Plastics Engineering Handbook 2nd Edition: Processing and Materials, Editor Myer Kutz, PDL, 2016.

Functional Fillers for Plastics (Chapter 23) C. DeArmitt, Applied Plastics Engineering Handbook 2nd Edition: Processing and Materials, Editor Myer Kutz, PDL, 2016.

Fillers (Including Fiber Reinforcements) (Chapter 8) R. Rothon and C. DeArmitt, Brydson's Plastics Materials, 8th Edition, M. Gilbert Editor, Butterworth-Heinemann, 2016.

Patents

EP 1 582 136 Dishwasher Provided with a Hot Warning Device for the Temperature of the Dishes Christopher Lynn DeArmitt, Fabio Spizzo

DE 10 2005 027 547 Polymer films with improved scratch-resistance Dr. Chris DeArmitt, Asimina Kavarnou, Dr. Graham Edmund McKee, Steffen Funkhauser

DE 10 2005 046 818 Tough, filler-containing styrenic polymer based materials Dr. Graham Edmund McKee, Hans-Jürgen Renner, Dr. Daniel Wagner, Dr. Chris DeArmitt

DE 10 2006 011 074 Polymer blend, useful for the production of foil, molded body or fiber, comprises acrylate rubber modified vinyl aromatic copolymer, glycol modified PET, phase

mediator and fibrous- or particulate fillers Dr. Chris DeArmitt, Dr. Graham Edmund McKee, Robert Huber, Dr. Michael Breulmann

EP 1 770 114 Sound damping sheets based on styrenic SBS polymers Chris DeArmitt, Konrad Knoll, Robert Huber

WO 2006/048168 Method for Producing Polymer Compositions Containing Mineral Oil and a Filler Christof Mehler, Chris DeArmitt, Philippe Desbois, Norbert Niessner, Claudius Schwittay, Jürgen Koch, Hans-Dieter Schwabe

WO 2006/053711 Tenacious Moulded Masses Containing Fillers and Based on Styrol Polymers Graham Edmund McKee, Hans-Jürgen Renner, Daniel Wagner, Chris DeArmitt

WO 2007/113297 Method for Coagulating Aqueous Polymer Dispersions Chris De Armitt, Graham Edmund McKee, Konrad Mitulla

WO 2007/118788 Continuous Process for Performing a Chemical Reaction in which a Gaseous Phase is added to a Charge Stream Comprising one or more Solid Phases which have been Dissolved or Dispersed in Water Wolfgang Fischer, Rainer Bardon, Chris DeArmitt

WO 2007/118796 Continuous Process for Performing a Reaction Chris De Armitt

WO 2008/031719 UV-Stabilizers for Plastics Chris DeArmitt, Graham Edmund McKee, Moritz Ehrenstein, Norbert Mosbach

WO 2008/065133 Method for Producing Dyed Textiles Comprising Polypropylene Fibres Claudia Sierakowski, Chris DeArmitt, Hans-Helmut Görtz, Martin Weber, Philippe Desbois, Helmut Reichelt, Peter Poganiuch

EP 1 985 663 Moulded Article with Temperature Dependent Transparency Chris DeArmitt, Graham Edmund McKee

WO 2015/031629 Dynamic Tactile Interface Micah Yairi, Christopher DeArmitt, Michael Hammersley

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A downloaded copy of the article and video are on file and are available upon request