POLYPROPYLENE RESIN & MESH DESIGN

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Dr. Chris DeArmitt - President
Polypropylene (PP) is a material that is unequivocally proven to be unstable, even at room temperature. It rapidly oxidizes causing cracking and catastrophic loss of mechanical properties, including strength. However, PP, when designed correctly for its intended end-use, can last decades. This is achieved by the addition of antioxidants. Antioxidants can allow PP to survive long term, if the correct type and amount of antioxidant are used. Thin items like fibers require more antioxidant. PP in aqueous environments requires even more antioxidant and of a certain type that is designed not to migrate. Thus, thin fibers of PP in an aqueous environment, i.e. the human body, is the worst case scenario for PP stability.

Because the ability of the PP mesh to survive in the body depends directly upon the amount and type of antioxidant used to stabilize it, we have used four different methods to determine whether the antioxidant is sufficient to protect the PP for several decades.

1. We have analyzed published data on stabilization of PP fibers exposed to water. The analysis clearly shows that the amount of stabilizer in Marlex® HGX-030-01 is only enough to protect the fibers for 2-4 years in water. We also compared the antioxidant package to other mesh implant PP. Ethicon’s mesh for example, which Boston Scientific set out to copy,\(^1\) contains 20 to 40x more antioxidant than Boston Scientific’s mesh. Ethicon attempted to formulate their mesh for long-term durability, whereas Boston Scientific made no such attempt.

2. We performed extensive testing using the industry standard oven ageing method to see whether the Boston Scientific’s mesh has enough stabilizer to survive for decades in dry conditions. We observed short failure times of <70 hours indicative of very poorly stabilized material. Properly stabilized PP would give over 1000 hours under the same conditions.

3. We compared the mesh to commercial PP items such as washing machines, pipes etc. that are designed to last 20-100 years in aqueous environments. Marlex\(^{\circledR}\) mesh has just 1/20\(^{th}\) to 1/40\(^{th}\) of the antioxidant used in such items.
4. We are performing tests on Marlex® mesh and directly measured its behavior in contact with saline solution to mimic conditions in the body. Those results to be established at when testing is complete.

Extensive, repeated analysis has conclusively proven that the amount of stabilizer in the Marlex® HGX-030-01 mesh is utterly inadequate. Specifically, 20-40 times more antioxidant is normally used for long-terms stabilization of PP. Furthermore, better antioxidants are available and are required for thin PP items in contact with water but these types were not used in the Boston Scientific’s pelvic floor mesh.

The claim has been made that PP is inert. As discussed above, any competent polymer scientist would concede that PP is readily oxidized and is therefore not inert. PP is not inert if oxygen is present and it is present in the body. PP in vivo has been shown to degrade and lose strength. Therefore, it is not inert in the body.

The claim has been made that PP is biocompatible. The fact that it causes a pronounced and prolonged immune response proves that it is not biocompatible. Biocompatible materials are known and they cause no such response.
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**Scope of Work**

Phantom Plastics LLC was retained by Mostyn Law, plaintiff’s council, to investigate and report on polypropylene mesh regarding its properties, durability and suitability as a material for permanent implants.

**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.

Dr. Joseph Webster
Dr. Webster obtained his undergraduate degree from the University of Houston and a PhD in Chemistry from the University of Texas.

Dr. Webster’s career has included positions in Sales, Technical Service, Patents, Technical Marketing, Product Development, Lab Management, Research and Development and Analytical Support. He has worked for Wheaton Plastics, Shell Development, American Cyanamid (now Cytec Industries), Sandoz Chemicals (now Clariant Corporation).

Currently, Dr. Joseph Webster is President of Stabilization Technologies LLC, a company located in Charlotte, North Carolina. Stabilization Technologies is a provider of contract analytical, product design and problem solving services for the plastics and coatings industries. Stabilization Technologies LLC is an international company with clients in China, India, Europe, Canada, Latin America and the United States.

His academic and professional achievements include substantial IP matter and publications over the last 35 plus years in the area of polymer science. He is the recipient of the American Chemical Societies Innovation Award in Industrial Chemistry for the SW United States in 2002 for his work in Molecular Modifiers™ and supramolecular Chemistry of condensation polymers.
Dr. Webster’s recent accomplishments include the development of new molecular modifiers for polyolefins, styrenics, and condensation polymers. Other developments include a high solids ballistic injection molded projectile for the military, OMPF pigment fillers, microwave and infrared absorbers, and solutions for the adverse effects of nano fillers on polyolefins. More recent developments are in the stabilization of essential oils and heat or light sensitive additives including colorants for plastics.

In the last five years, he has received numerous patents in the fields of molecular modifiers, fillers and additive stabilizer systems for condensation polymers. Another revolutionary product is sulfur black which allows for polyolefin stability beyond that attainable using conventional stabilizers and carbon black. This last product is of particular interest for under-the-hood automotive parts. Most recently, Dr. Webster won an Innocentive Open Innovation Challenge related to odor reduction in plastics.
Introduction

Polymer science is a field of its own and the stability of PP has been studied for several decades. There is a solid body of peer-reviewed, scientific evidence to indicate the conditions under which PP is stable and the conditions that will lead to failure. For example, ScienceDirect.com lists 707 articles on PP oxidation.

The rules of chemistry do not cease to exist when PP is implanted in the human body. Boston Scientific are aware that PP is susceptible to oxidation and yet no apparent long-term testing has been performed to verify its durability and suitability of PP for implant applications. Despite that, the material has been “grandfathered in” under the assumption that it is safe.

Over recent years, many complaints have arisen from patients implanted with PP mesh. This has led to closer scrutiny of the PP material. Attention has been focused on analysis of explanted material to look for any signs of material degradation. There have been multiple reports that oxidation of the polypropylene has occurred in vivo, leading to cracking and weakening of the fibers. At some point the strength becomes reduced so significantly that the fibers lose their load-bearing capability and fail.

This report explains what is known about PP and its ability to survive in long-term applications such as in medical implants.
The stability of polypropylene for long-term use

Pure polypropylene (PP) is very unstable and is rapidly oxidized at room temperature. That is well proven and beyond question, as shown below. Oxygen in the air reacts chemically with polypropylene and that reaction breaks the polymer chains rendering the polymer weak and brittle. At room temperature, pure PP, so-called “unstabilized” polypropylene becomes brittle and loses its strength in about one year. This has been known ever since the first commercial PP was made several decades ago. Because this is such a crucial point, we will reinforce it by citing statements from several sources.

- “Without stabilizers the rate of degradation of PP is so fast as to make this polymer unsuitable for most purposes.”
- “Even at room temperature unstabilized PP loses its mechanical strength within a year.”
- “The sample, originally flexible, broke upon bending after storage of approximately 2 years (this was at room temperature, i.e. 21°C.) Rapid oxidation and molecular weight loss (breaking of the polymer chains) occurred in under 500 days at 21°C (i.e. room temperature).”
- “Virgin PP directly from a commercial process is very susceptible to air oxidation.”
- The oxidation resistance of polypropylene is very poor, so much so that it is impossible to process PP under commercial operating conditions without antioxidant.
- “Pure polypropylene is not very stable at the melt temperature and degrades at room temperature…” and goes on to say “So preparation of commercially useful polypropylene fibers requires addition of stabilizers to permit processing and adequate life…”

Other studies have shown that unstabilized PP oxidized in just 16 hours at 100°C and 440 hours at 70°C and in 1500 hours at 60°C. Thus, any claim that PP is inert and oxidizes only at high temperature is completely disproven. In fact, even at room temperature, i.e. below body temperature, PP oxidizes quickly.
PP is so unstable that in the early days, accidents occurred. A pile of powder left in the summer heat began to oxidize, which heated up the polymer even more, so it oxidized even faster. This accelerating oxidation generated so much heat that the polypropylene melted, which is astonishing because the melting point of polypropylene is 165°C (330°F).

Oxidative degradation is a known weakness of PP and is often the cause of failure. The chemical reactions are well-understood and are the result of free radicals which are extremely reactive chemicals created when molecules are torn into two pieces. They can be found in flames and in smoke, for example. They can damage DNA (a polymer) leading to mutations and cancer. Free radicals can be formed when UV light hits polypropylene or people for that matter. Free radicals can damage people and they are also very harmful to PP.

When it comes to PP, the question is not whether it will fail. It is certain to fail. The question is “when will it fail?” The answer to that question depends on the amount and types of antioxidants used.

Selection of the appropriate antioxidant or antioxidant combination depends on the performance required during processing and the application requirements. The selection of proper antioxidants and antioxidant combinations depend on the performance required during processing and the application requirements. It is extremely important that the correct primary and secondary stabilizers be selected for the end use application of the polymer and lifetime.

Polymer manufacturers only purchase and use enough stabilizer to allow them to sell a general grade capable of meeting minimum requirements for typical high volume, commodity applications. The goal is to provide all necessary stabilizing properties to the resin without adding more than is necessary for the end use because adding extra stabilizer costs money and adding too much would make their commodity PP resin uncompetitive. Such resins with a low level of antioxidant are often called “barefoot” resin. For more demanding applications, where long-term stability is needed, it is up to the manufacturer of the finished product to add extra stabilizers and other additives. That is what we did when I worked at Electrolux (Frigidaire), for example.
There are hundreds of PP additives and therefore thousands of combinations in both type and amount. Companies should carefully select additives needed to ensure that the product lasts over its effective lifetime.\(^\text{14}\)

The choice of additives depends upon expert opinions and experience.\(^\text{15}\) It is important that consumer product manufacturers produce PP articles with the best commercial antioxidants for a particular application, so tapping the expertise of a plastics supplier, antioxidant supplier, or plastics expert, is crucial when deciding a formula for a specific application.\(^\text{16}\) This is especially the case in instances where the manufacturer of finished product does not have their own internal experts on staff.

We will look in detail at the types and amounts of antioxidants in the PP raw material and the finished mesh because they are crucial to understanding the case.
Antioxidants / stabilizers for polypropylene

There are many types of antioxidant and they each have a different function or behavior. Hindered phenols like the Irganox family are the main antioxidants used to provide long-term stability. Phosphites, like Irgafos 168, are the main process stabilizers which protect the phenolic and keep the polymer intact at high temperature when it is molten and being processed into a fiber for example. Here is table that summarizes the various types and their uses (Table 1).

<table>
<thead>
<tr>
<th>Stabilizer Type</th>
<th>Effectiveness</th>
<th>Detectability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>During processing</td>
<td>Long-term</td>
</tr>
<tr>
<td>Hindered phenol</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hindered amine</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Phosphite</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Thioester</td>
<td>✗</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Table 1 Types of stabilizer, their effectiveness for ageing and in accelerated ageing tests*

Boston Scientific’s pelvic floor mesh cleared by the FDA is made from Chevron’s Marlex® HGX-030-01 and contains Irganox 3114 (a hindered phenol) as a long-term stabilizer and Irgafos 168 as a processing stabilizer. The ability of the mesh to resist oxidation in the body is solely determined by the hindered phenolic antioxidant. Two questions must be asked.

1. Is the hindered phenol the correct stabilizer to use in this application?
2. Is there enough stabilizer to protect the mesh from degradation?

There are different ways to answer that question. Rather than rely on one method, we decided to be more rigorous and look at it from four different perspectives. Considering the information from different angles ensures a reliable conclusion.
Durability of Marlex® Mesh

As we have seen, PP is certainly not inert. It is attacked by oxygen and will fail after some period of time. The failure time depends on the types and amounts of antioxidant (stabilizers) used. This section of the report uses four different methods to estimate the lifetime of the PP mesh.

Hindered phenolic antioxidants are able to protect the PP from oxidation until the antioxidant is used up. When the antioxidant is gone, then the PP becomes unstabilized and will fail shortly thereafter (Figure 1). The antioxidant can be used up fighting radicals in the polymer, or it may simply be lost by evaporation or it may be washed out by water, for example.

![Figure 1 Hindered phenol antioxidants give excellent protection until they are gone](image)

The detectable concentration of stabilizers decreases steadily until a critically low concentration is reached and then it becomes susceptible to catastrophic oxidative degradation of the mechanical properties and failure occurs. A consequence of this is that PP gives the illusion of being stable. For example, you may find that the PP looks perfect after 1 year, 2 years or 5 years and then loses all of its strength and fails completely before reaching year 6.
It is also important to note that antioxidant is being used up every day. The PP pellets in storage are losing antioxidant slowly day by day, i.e. they have a finite shelf-life. Processing, or extruding, the PP pellets into fibers that can be woven into PP mesh uses up a significant amount of antioxidant (typically a few hundred ppm). The antioxidants are sacrificed protecting the PP at the high temperatures needed to extrude the pellets into monofilament fiber that can be spun and woven into mesh to build Boston Scientific’s pelvic floor products.

It is vital to know the antioxidant concentration at all stages of the storage and manufacturing process because that antioxidant is all that is protecting the PP mesh in the body. How much antioxidant is in the PP pellets? How much is left after storage? How much is left after spinning and weaving the fibers to make mesh? How much is left after the mesh has been stored for a period of years? There is no evidence that any of these questions were addressed by Boston Scientific. For a young lady receiving a mesh implant in her 20’s and average life expectancy for females in the USA being over 80 years, we can conclude that the mesh needs to be guaranteed to survive for over 60 years.
Method 1 – Best Practices

One way to look at the stabilization of the mesh is to compare the stabilizer package to other commercial polypropylene items designed to last for decades. Some examples are tabulated below (Table 2). The antioxidant types and concentrations are given.

<table>
<thead>
<tr>
<th>Application</th>
<th>Long-term Stabilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polypropylene</td>
<td></td>
</tr>
<tr>
<td>Washing Machine &gt; 20 year service life (Thick part)</td>
<td>Hindered Phenol 900</td>
</tr>
<tr>
<td></td>
<td>Thioester 2600</td>
</tr>
<tr>
<td></td>
<td>Total 3500</td>
</tr>
<tr>
<td>Sewer pipes &gt; 100 year service life (Thick part)</td>
<td>Hindered Phenol 1000</td>
</tr>
<tr>
<td></td>
<td>Thioester 2400</td>
</tr>
<tr>
<td></td>
<td>Total 3400</td>
</tr>
<tr>
<td>Geomembrane &gt; 20 year service life (Thin film)</td>
<td>Hindered phenol 3000</td>
</tr>
<tr>
<td></td>
<td>Hindered amine (HALS) 5000</td>
</tr>
<tr>
<td></td>
<td>Total 8000</td>
</tr>
<tr>
<td>PP Mesh 100 year service life (Thin fiber)</td>
<td>Hindered Phenol 100-250</td>
</tr>
<tr>
<td></td>
<td>Other long-term stabilizer 0</td>
</tr>
<tr>
<td></td>
<td>Total 100-250</td>
</tr>
</tbody>
</table>

Table 2 Antioxidant amount used in typical commercial applications of PP compared to the PP mesh

The Marlex® HGX-030-01 mesh contains only about 200ppm (parts per million) of antioxidant (0.02% by weight). We see that thick parts designed to last 20 years or more typically contain 3500 ppm of antioxidant. Thinner parts oxidize much more quickly so more antioxidant is needed. A geomembrane is one such example. PP geomembranes are stabilized with 8000ppm of antioxidant, about 40x more than is found in the mesh. Furthermore, a special type is used (high molecular weight HALS), in order to prevent the antioxidant from being washed out of the PP by water exposure.

Using this comparison, we can conclude that the Marlex® HGX-030-01 is drastically under-stabilized for long term use. We can also see that there was a failure to choose the correct type of antioxidant, namely high molecular weight HALS such as Chimassorb 944. Sean Curran of Boston Scientific claimed that he
was unaware that HALS stabilizers such as Chimassorb 944 could be used to provide long-term thermal stability to PP. That claim is hard to reconcile with the fact that Curran circulated a peer reviewed scientific article showing that Chimassorb 944 was an excellent stabilizer for PP fibers exposed to water where it dramatically outperformed the hindered phenolic types.

It is also informative to compare the stabilization of mesh made from Marlex® HGX-030-01 to other mesh on the market. For example, Prolene® mesh from Ethicon (part of J&J) contains the following stabilizer types and amounts.

<table>
<thead>
<tr>
<th>Material</th>
<th>Pellets</th>
<th>Fiber</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antioxidant</td>
<td>Amount (ppm)</td>
</tr>
<tr>
<td>Marlex® HGX-030-01</td>
<td>Irganox 3114</td>
<td>&lt;700</td>
</tr>
<tr>
<td></td>
<td>Irgafos 168</td>
<td>&lt;700</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>&lt;1400</td>
</tr>
<tr>
<td>Ethicon Prolene®</td>
<td>Santonox R</td>
<td>1000-3000</td>
</tr>
<tr>
<td></td>
<td>DLTDP</td>
<td>4000-6000</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>5000-9000</td>
</tr>
</tbody>
</table>

The Prolene® mesh contains approximately 40x as much long-term stabilizer compared to the Marlex® mesh, which barely contains any. Ethicon chose to use a combination of hindered phenol (Santonox R) and a thiosynergist (DLTDP) because that combination is known to give longer life than using hindered phenol on its own. Ethicon have recognized that the mesh is exposed to very severe conditions in the body and so they have added a large amount of stabilizer plus a synergistic additive to further boost performance.

In conclusion, by comparing to what is known to work in other applications we see that the Marlex® mesh is drastically under-stabilized and contains between a twentieth and one fortieth of the stabilizer we would expect to find for a well-
stabilized PP. Furthermore, only one long term stabilizer was chosen when far better results can be achieved with a combination.

By Method 1, the Marlex® HGX-030-01 mesh fails by a very large margin.
Method 2 – By the Industry Standard Oven Ageing Test

The best way to tell if a plastic part will survive for a long period in a certain application is to test the part under those exact conditions. Ideally, a PP dishwasher part would be tested for 20 years in a dishwasher and then, if it passed the test, it would be approved for use and the manufacturer could start making dishwashers using that material. In reality, we usually cannot afford to wait 20 years for the results. Therefore, it is common practice to do accelerated testing to get an estimate about whether the plastic will last or not. Such tests are laid out in standards such as ASTM D3012-13, ISO 4577, ASTM D3045 and ASTM D5721 among others.

There are different ways to accelerate the polymer oxidation. One way is to increase the temperature. Another way is to increase the amount of oxygen, i.e. expose the polypropylene to pure (100%) oxygen instead of air which contains about 20% oxygen. One can do both at the same time, i.e. increase the temperature and the oxygen concentration.

Many methods have been tried. A method called oxidation induction time (OIT) was tried because it is very quick and easy. OIT involves heating to very high temperature (190-200°C, around 390°F) under pure oxygen. However, it was found that the test was too far away from real world conditions and did not predict actual stability of the polymer in use. For that reason, OIT is not accepted for long term stability testing and is not used by any competent polymer scientist. To illustrate the point, an OIT test might last 5 or 10 minutes. It should be obvious that a test that short is not going to predict how the plastic behaves over a period of 50 or 100 years. I conferred with several top polymer stabilization experts who were asked whether OIT is valid for predicting long term polymer stability.

The experts were Professor Norman Billingham, former Editor of the journal Polymer Degradation and Stability. Professor Graeme George, current editor of Polymer Degradation and Stability. Dr. Peter Gijsman, a leading expert in polymer stabilization working at DSM. Svein Jamtvedt, an expert with decades of experience in polypropylene stabilization, currently at Norner. Dr. Duane Priddy Sr., a leading plastics expert retired from Dow and owner of Plastics Expert. Professor Ulf Gedde from KTH Stockholm who has worked extensively on polymer stabilization.
I conferred with each expert individually and in each case their independent opinion was that OIT is most definitely not valid for predicting long-term polymer stability.

The invalidity of the OIT method for long-term prediction is mentioned here because, as we will see later, Boston Scientific rely on it. Ironically, in his April 2017 deposition Dr. Sean Curran from Boston Scientific said “no-one in their right mind” would rely on oven ageing results at 150°C because the temperature is too high to be realistic. That is odd as they use OIT at 200°C or higher and somehow believe that to be valid.

The one method that is accepted and has been shown to most closely predict long-term oxidation stability in common plastics application is the oven ageing method. Using the oven ageing method, PP is heated up in air and the time to failure is measured. It is a better method for four reasons:

1. The test is performed in air, which is more realistic that using pure oxygen;
2. The test is performed at lower temperatures than OIT and the lower temperatures are closer to the real use temperature;
3. The test is performed on solid polymer whereas in OIT the plastic is a molten liquid, which is unrealistic; and
4. Oven ageing takes much longer than OIT, for example oven ageing can take hundreds of hours compared to a few minutes for OIT.

Having established that oven ageing is the industry standard method for predicting long-terms stability of PP, we can look to see what it tells us about the Marlex® mesh. Firstly, we should note that Boston Scientific has done no oven ageing of its mesh or products to failure which means they have no conclusive data on the long-term behavior of their mesh. Boston Scientific did only arbitrary shelf life testing of its products up to 37 months. That is remarkable because automotive manufacturers, household appliance companies etc. all do oven ageing to ensure their product will last as long as it needs to. Taking the example from above for the antioxidants used in a washing machine, the specification is that the polypropylene needs to survive 850 hours at 150°C in an oven to ensure a 20 year lifetime of the PP parts at room temperature. On that basis, Marlex® mesh would need to have an oven ageing time of several thousand hours if the mesh is to survive for 60-80 years. Dr. Joseph Webster of Stabilization Technologies, LLC tested the oven ageing stability of the Marlex® mesh and
found it to survive <70 hours (based on multiple samples). This result is consistent with the very low levels of antioxidant in the Marlex® mesh. Additionally, the Marlex® has to survive in the body which is warmer than room temperature and exposed to liquid in the body, both of which accelerate oxidative failure. The oven ageing confirms that the stabilization of the Marlex® mesh falls far short of the 60-80 year lifetime needed.

By Method 2, the Marlex® mesh fails by a very large margin.
Method 3 – By Comparison with Published Data on PP Fiber Stability

Scientific literature has looked in detail at the oxidative stability of PP fibers. One published study compared PP fibers that contain various types and amounts of stabilizer. As well as oven ageing, they examined the oxidation of PP in water. Because these studies were done at relatively low temperatures of just 80 & 90°C and because they are in water, they are highly relevant for predicting the stability of PP fiber mesh in the body.

The first critical finding of the study was that PP fibers oxidize and fail much faster in water than they do in air at the same temperature (Figure 2). That is backed up by many other studies on polymer stability. Why does polypropylene oxidize so much faster in water? It turns out that the antioxidant gets washed out of the PP by water. The technical term is migration. Migration of antioxidant out of water pipes and other parts is a major problem and that is one reason why it has been studied in such detail. Antioxidants can also migrate out of plastics and into food, another topic that has been closely studied.

![Figure 2 Oxidation of PP fibers in water is much faster than in air due to antioxidant loss into the water](image-url)
In that study on PP fibers, the OIT method was used to measure the amount of antioxidant in each sample as the polymer was aged at 80°C. It should be noted that OIT is valid for measuring antioxidant concentration between samples containing exactly the same type of stabilizer. The graph shows that this PP fiber, which had high levels of antioxidant, was stable for over 450 days in the oven ageing test. However, when exposed to water at the same temperature, the antioxidant was gone, washed away by the water, in just 100 days (Figure 2).

We can see that the PP fibers that were stabilized using only hindered phenols, all reached zero antioxidant and zero stability, i.e. failure, in a few hundred days at 80 and 90°C. Samples 2 (Ba) and 3 (Cb) in the article contained 4000 and 5000ppm of hindered phenol, which is over 20 times more than the Marlex® mesh. Based on that, we can expect that the mesh would last just 1/20th as long in water. For example, we can estimate that Marlex® would last around 1/20th of the 1000 days that sample 3 survived, i.e. the Marlex® would resist oxidation for 50 days at 80°C. How long would the Marlex® mesh survive at 40°C i.e. body temperature? There is a rule of thumb that reactions happen 2x slower for every 10°C drop in temperature. While that approximation is far from perfect, it has been cited by Boston Scientific so we will apply it here. 40 days at 80°C would translate to 50x2x2x2x2=800 days. That means we would expect Marlex® mesh to last just over 2 years at 40°C surrounded by water inside the body.

Migration of antioxidants has been shown to be dominate the stability of polymers. A study on pipes said that “the chemical consumption of phenolic antioxidants was negligible compared to the physical loss of antioxidant at temperatures between 70 and 110°C”. They are saying that the antioxidant is lost so quickly that it cannot do its job in protecting the polymer.
That pipe study\textsuperscript{38} showed that the antioxidant concentration, as measured by OIT, decreased by 70% in just 1104 hours contact with 75°C water.\textsuperscript{38} It also showed that the plastic surface in contact with water can have much lower antioxidant concentration than is found deeper inside the part. That is important because the PP mesh fibers are very thin, less than 200 microns in diameter, so we know that antioxidant will be rapidly lost from the fibers. As soon as the antioxidant concentration gets too low, the PP is unstabilized and failure will occur shortly thereafter.

**By Method 3, the Marlex\textsuperscript{®} mesh fails by a very large margin.**

That article on oxidation of PP fibers in hot water\textsuperscript{38} shows that hindered phenols alone do not provide adequate protection for PP fibers in contact with water. The same article showed that dramatically improved stability can be achieved simply by adding a second type of antioxidant, such as a high molecular weight HALS called Chimassorb 944. That type of stabilizer is so large that it doesn’t migrate into water and that makes a huge difference to the survival of the PP fibers.

Members of staff at Boston Scientific were aware of that study on PP fibers in water. That means that Boston Scientific presumably knew that:

1. Hindered phenols are not enough when used alone
2. PP fibers exposed to water need very high amounts of stabilizer
3. Addition of high molecular weight HALS gives far better stability

Interestingly, in Sean Curran’s deposition in April 2017 he claimed that he did not know HALS can provide long term stability to PP. Yet we see in an email where he referred to that same article showing that HALS work and are far superior to hindered phenols. They could have used that information to produce a far better mesh product but instead they ignored it.

Did Boston Scientific know that Marlex HGX-030-01 was not suitable as a permanent implant material? We can see from the Marlex Materials Safety Datasheet (MSDS)\textsuperscript{39} in their possession that they did know. The MSDS shows the following.
Chevron explicitly warn not to use Marlex® for permanent implantation in the human body or in contact with body fluid. Why do they do that? Clearly, because they know that there is not nearly enough stabilizer in the Marlex® to protect it for permanent use. The antioxidant will migrate out into the fluid and be rapidly used up protecting the polymer.

Interestingly, Chevron go on to state that Marlex® can be used for temporary implantation if you contact them first and receive the material directly from them. They are willing to approve temporary use because there is enough stabilizer there to protect the PP for a limited time.

This implies that they are warning against use of Marlex® for permanent implantation on technical grounds. If they were simply trying to avoid legal liability, then they would not have sanctioned use in temporary implantation.
We decided to look at the article they referred to as evidence that the Marlex® HGX-030-01 would have a long shelf-life. The paper mentions that the polypropylene is highly stabilized with Irganox 1330. The OIT measurement performed at 200°C gives a result of over 20 minutes of stability. By comparison, the Marlex® HGX-030-01 pellets are stabilized with Irganox 3114 and have an OIT at 200°C of under 6 minutes. However, OIT cannot be used to compare PP stabilized with two different stabilizers.

In fact, the PP mentioned in the paper has a longer OIT after 23 years storage than new Marlex® pellets have. Thus, it is not possible to use the stability results from the highly stabilized PP in that article to verify the stability of Marlex® which contains far less stabilizer.
In conclusion, the paper they cite cannot be used to confirm a long shelf-life for Marlex® HGX-030-01 pellets. In fact, if we look at the data in the article, it shows that the OIT is reduced by 6 minutes for every 6 years that the PP is stored at room temperature. Based on the fact that the Marlex® pellets have an OIT of 5-6 minutes when new (see Cambridge Group report), Boston Scientific’s own argument would indicate that the particular Marlex® HGX-030-01 pellets analysed have a shelf-life of just six years before the antioxidant would be all used up.

That prediction is not precise when applied to US Marlex® because it contains a different stabilizer than the one used in the article. However, the China Sourced Resin contains the exact same stabilizer, Irganox 1330, as used in the article so we can predict with some certainty that the China Sourced Resin pellets samples here will have a shelf life of just 6 years. If we look at the mesh made from China Sourced Resin we have just half the amount Irganox 1330 left meaning that the expected life of that mesh would be just 3 years at room temperature and even less than three years in the body. That is far too short compared to the requirement of over 60 years.
Incredibly, although Boston Scientific have looked into the topic of shelf-life of the pellets and the mesh, they have put no attention at all into the durability of the PP inside the human body (Rao deposition). They have even testified that no testing at all was done to gauge the resistance of PP mesh to oxidation and failure when implanted. This is a glaring and shocking admission. Can it be that they only care that the fiber looks fine up until implantation and do not care about the fate in the body? That is what the facts suggest.

The diagram shows how the long-term stabilizer is depleted over time. It can be seen that the entire history of the plastic makes a difference (Figure 5). For example, how long the pellets are stored, the processing temperature, how long the spun fiber is stored and so on. A large proportion is already used up before the fiber is even implanted. Once it enters the body, the stabilizer is depleted faster than in storage for two reasons. Firstly, the water in the body extracts the antioxidant so it is no longer in the fiber and cannot protect it. As well as that, what little antioxidant is left in the fiber is consumed as it fights the radical attack from the biological response to a foreign object.
Here is an example of an attempt to arbitrarily extend the shelf-life of the PP yarn used to make mesh. Firstly, they admit that the 10 year shelf-life was not based on any data and was simply made up to satisfy their SAP computer program.

74. 12.19.06 - SHELF LIFE - Shakespeare Polypropylene Monofilament Yarn Shelf Life Extension - Technical Support - BSCM19800000037 (004)

Anthony J. Soroka December 19, 2006

“The current 10 year shelf life of the existing Shakespeare polypropylene monofilament yarn was defined on an arbitrary shelf life input into the SAP system and not on any inherent property or performance characteristic of the material.”

They then go on to say:

“A 10 year extension of the shelf life for the Shakespeare fully drawn crystallized polypropylene monofilament yarn (Material Number 34106700) is supported based upon the fundamental polypropylene polymer and yarn technology. The key open literature references (Handbook of Fiber Chemistry, Physical Properties of Textile Fibers, and Man Made Fibers) describe the inherent stability and long shelf life potential of fully drawn crystallized polypropylene yarns when stored under the BSC Wayne conditions of relatively low temperature, humidity, and in the absence of direct exposure to UV light (Attachment I).”

The problem is that when you look at the books their experts cite, they do not support the claims they make.

The book Man Made Fibers states:

i.e. this says nothing about the stability of PP in air, during storage.

The book Physical Properties of Textile Fibers does not contain a single word about the storage or oxidative stability of PP.
Lastly, the Handbook of Fiber Chemistry, 2nd Edition in Chapter 3 Polypropylene Fibers says the exact opposite of what they claim. Instead of saying that PP fibers are stable, the books says on page 162:

Polypropylene generally leaves the reactor as a powder which, after separation from unreacted propylene and/or solvent, is quite susceptible to oxygen, even at room temperature. Antioxidants are required to protect the powder during storage, and additional antioxidants may be needed to permit it to be melted for extrusion, either to form pellets or to be spun into fiber. Once formed, the fiber must be protected by a long-term antioxidant (which may or may not be different) that will help protect the fiber during its useful lifetime. Additional stabilizers may be needed depending upon the fiber end use. Exposure to UV light (sunlight) in the presence of atmospheric oxygen will

On page 183 it goes on to say.

5. ADDITIVES FOR FIBER PREPARATION

Pure polypropylene is not very stable at the melt temperature and degrades at room temperature, particularly in the presence of UV light; and it is not dyeable: coloration requires the addition of pigments. So preparation of commercially useful polypropylene fibers requires the addition of stabilizers to permit processing and adequate life and the addition of pigments to provide the color. Additives to modify the resin are essential for polypropylene fibers; the choice of additives is extensive, so that a wide variety of properties have been designed into polypropylene fibers by the use of additives. Since the additives—both stabilizers and pigments—interact with one another, the entire additive package must be considered when trying to achieve a particular set of properties. The mechanism by which unstabilized polypropylene degrades has been studied extensively and provides some understanding to how stabilizers function.

Thus, it is generally known to those in the polymer and fiber industry that PP degrades even at room temperature. It says that antioxidants must be used. Furthermore, when pigments are added, as they are for blue fibers, the antioxidant may not perform as well and this must be checked and adjusted for. We can find no evidence that Boston Scientific checked whether the pigment would shorten the lifetime of the fibers.

Next it states:
5.1 Stabilizers

Mechanism of Unstabilized Fiber Degradation

More than any other polymer used to prepare fibers, polypropylene owes its existence as a fiber-former to stabilizers used to overcome its deficiencies. As prepared, polypropylene is unstable to both heat and light. At the high temperatures used to melt the resin for fiber extrusion, polymer molecular weight and melt viscosity change, creating processing difficulties. During extrusion, polymer reactions occur that result in oxygen-containing groups becoming part of the polymer [43]. As a fiber, unstabilized polypropylene is very susceptible to sunlight-initiated deterioration. Weathering results in a sharp drop in fiber elongation together with an increase in oxygen-containing groups.

Thus, PP owes its “existence as a fiber-former to stabilizers used to overcome its deficiencies.”

This textbook directly and repeatedly contradicts Boston Scientific’s experts claim that PP is stable.

On page 185 the book shows data on multiple processing of PP stabilized with Irganox 3114 (formerly known as Goodrite 3114).
This data shows that every time the PP is extruded, the polymer chains are broken which reduces viscosity and increases the flow rate (Melt Flow Index). This is another indication, that even when stabilized using the same stabilizer found in Marlex HGX-030-01, the PP degrades. This is an important point because we have discovered that during production of Boston Scientific PP mesh fiber, the scrap fiber was intentionally mixed back in with the virgin pellets. That is commonly done when making low cost, non-critical or disposable products in order to save money. Adding scrap back into the production process is not good practice when manufacturing medical implant devices.

Degraded PP, with a portion of its antioxidant used up, was added into the virgin PP material. This is expected to reduce the oxidative stability and service lifetime of the mesh.

The cavalier attitude to shelf-life is inexcusable. The antioxidant is depleted day by day. One cannot simply change the acceptable shelf-life at will and then defend the decision by citing books that do not support the change. To give some perspective, the cost to add a typical long-term antioxidant package, as shown in

<table>
<thead>
<tr>
<th>Antioxidant</th>
<th>Number of extruder passes at 270°C Melt Flow Indexa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Goodrite 3114</td>
<td>5.6</td>
</tr>
<tr>
<td>Irganox 1010</td>
<td>5.0</td>
</tr>
<tr>
<td>Topanol CA</td>
<td>5.0</td>
</tr>
<tr>
<td>Ionox 330</td>
<td>4.1</td>
</tr>
<tr>
<td>Irganox 1076</td>
<td>5.9</td>
</tr>
</tbody>
</table>

aASTM D1328.
the article on PP fibers is just $0.02 per pound of PP. Boston Scientific sell the PP mesh for tens of thousands of dollars per pound so the cost to add antioxidant would have been minimal.
Method 4 – By Stability Testing of Marlex® Mesh in Saline Solution
Testing underway.
Biological Stability of Polypropylene

There is a mistaken assumption that PP is inert, i.e. unreactive in a biological environment. That is because people see PP articles like water cups, Tupperware containers and so on in their everyday life. As these parts contain antioxidant and do not visibly degrade, they give the impression that PP is stable. As we have seen, PP is highly susceptible to oxidation in air, even at room temperature and it is only the antioxidant that prevents rapid failure. What is known about the stability of PP to microbes or in the body? Work on those topics has already been done and reported in the scientific literature. For example,

- In 1976 Liebert examined the fate of unstabilized PP fiber and PP fiber containing antioxidant in vivo\(^1\) implanted in hamsters. In that landmark paper, he found that the unstabilized PP fiber began to oxidize in just 50-90 days in vivo as confirmed by FTIR spectroscopy, changes in molecular weight and in mechanical properties of the fiber. In contrast, the PP fiber containing antioxidants did not oxidize or change mechanical properties for the duration of the test which was just 150 days. He concluded that the body attacks the polymer by oxidation. Even as far back as 1976 Liebert illustrated that a combination of hindered phenol antioxidant and thiosynergist (similar to that used today in Ethicon mesh) was able to extend the lifetime of PP in vivo.

- A study on Prolene\(^\circledR\) 2-0 suture implanted in rats showed that the polypropylene fiber lost 25% of its strength in just 6 weeks.\(^2\) That is a very important finding. The 2-0 Prolene suture is 300 microns in diameter, much thicker than the Prolene mesh fiber and even that thicker fiber was weakened in under two months.

- In a very detailed study entitled “Polypropylene as a reinforcement in pelvic surgery is not inert - comparative analysis of 100 explants” showed that all types of PP implants exhibited degradation.\(^3\) They also concluded that degradation is much more prevalent when infection present and more when inflammation present. This is important because PP causes an inflammation\(^4\) and the body attacks the foreign body using radicals leading to the degradation they observed. There are other studies on explanted PP mesh which also see report degradation and cracking due to oxidation.\(^5\)
• In 1998, dogs were implanted 2 different types of mesh (Marlex®, Bard and Soft Hernia mesh, Ethicon). Upon mesh removal, there was obvious folding of the material in 3 of the 5 dogs implanted with Marlex®, “which resulted in a pronounced increase in bending stiffness.” The Marlex® showed shortening by 25%, as well as shrinking of the mesh area of 46% after 4 weeks. The shrinking was reduced in the Soft Hernia mesh, having only shrunk about 34%. The authors also found that in general the main tissue reaction in both groups seemed to be completed after 2 months. After 6 months the pores of the Marlex® mesh markedly decreased in area by 47%, but the Soft Hernia mesh had only reduced by 28%.

• Other workers noted that the flora (bacteria) present around the pelvic implants are not present for abdominal implants, e.g. for hernia repair. The bacteria on the pelvic implant may cause additional inflammation and attack on the mesh implant.

• PP films have been placed in a landfill to see whether the PP was immune to attack. After just 11 months, the microorganisms in the landfill had significantly attacked the polypropylene film (see Figure 6).

![Figure 6 SEM micrograph of a PP film before (left) and after (right) eleven months burial in a landfill](image)
They verified that the PP was oxidized by FTIR spectroscopy. Clearly, polypropylene can be attacked in a biological setting. Another study exposed PP to microorganism in a laboratory setting and found significant weight loss and oxidation starting less than 50 days into the experiment. This raises the question about stability in vivo, i.e. in the body.

PP is broken apart by radical attack according to the well-known basic autooxidation scheme (Figure 7).

![Figure 7 Oxidation of polymer by an auto-accelerating radical attack](Image)

When a plastic part is placed inside the body it is detected as a foreign object and the immune system reacts and attempts to destroy it. Perhaps surprisingly, the body attacks by generating radicals and highly oxidizing chemicals like superoxide. This body response is well-documented and proven. Unfortunately, the body attacks the PP with radicals and oxidizing agents which are known to be the main weakness of polypropylene. That explains why PP has been widely reported to crack, lose strength and degrade in vivo.

Recently, workers have exposed PP mesh to oxidizing conditions designed to mimic those found in the body. They created hydroxyl radicals, the same type as the body immune response creates and submerged the PP mesh in a water
solution containing the radicals. Two Boston Scientific (Advantage™ and Lynx™) meshes and one Ethicon product (GynecareTVT™) were evaluated. They found oxidative degradation as indicated by FTIR spectroscopy, pitting of the fibers seen under a microscope and XPS was used to measure the oxygen reacted with the PP fiber surface. All this occurred in just 5 weeks.

Oxidative stability of PP in air is greater than in water but in the body the stability is even lower because of radical attack. Furthermore, it is well-known that iron and its compounds catalyze (accelerate) degradation of polypropylene. As the blood contains significant iron and enzymes in the body contain iron and other transition metals that catalyze oxidation, it would be reasonable to expect even faster degradation of polypropylene.

The synopsis of that article stated:

Superoxide and hydrogen peroxide can interact to form very toxic hydroxyl radical in the presence of iron. The data have shown that the hydroxyl radical is likely to be one of the main causes of polymer degradation in implantable devices. It can be seen that iron (Fe) catalyzes production of hydroxyl radicals (HO•) that attack polypropylene. Another reactive oxygen species (ROS) called superoxide is also formed (O₂⁻)

\[
O_2^- + H_2O_2 \rightarrow HO• + HO^- + O_2
\]

\[
O_2^- + Fe^{3+} \rightarrow O_2 + Fe^{2+}
\]

\[
H_2O_2 + Fe^{2+} \rightarrow HO• + HO^- + Fe^{3+}
\]

While it is clear that PP can be oxidized and weakened, no mention has been made so far about the chemicals formed when the PP oxidizes. PP is melted at high temperatures in order to form the fibers. Exposure to such temperatures has been shown to produce very toxic compounds including formaldehyde, acetone and acetaldehyde. The levels of toxins produced were found to have significant effects when rats were exposed to them. It is troubling that such toxic compounds may be in the fiber implant material and that the topic does not appear to have received any attention.

Aside from the overwhelming number of articles showing that PP degrades in the body, there was one recent article purporting to show that implanted PP fiber did
not degrade. We would like to address that article entitled “The myth: in vivo degradation of polypropylene-based meshes” by Shelby Thames et al.\textsuperscript{60}. Firstly, it uses an extreme and unproven method to clean the explanted fibers so one could argue that the cleaning removed any traces of oxidation. On that basis alone, the article is questionable and indeed it has been directly challenged\textsuperscript{61}. The Thames article was on Ethicon Prolene\textsuperscript{®} mesh which is highly stabilized in contrast to the Marlex mesh which has one twentieth the stabilization, so the oxidation behavior of two cannot be compared, i.e. it is not an “apples to apples” comparison. In fact, Thames correctly points out that his article on stability of Ethicon’s Prolene\textsuperscript{®} mesh is not applicable to other mesh for exactly that reason. Thames stated:

“Our findings are also limited to Prolene mesh and may not necessarily apply to other polypropylene formulations, because the types and concentrations of additives, particularly stabilizers, may vary among manufacturers/suppliers.”

Clearly, his articles cannot be applied to other PP products containing different types and amounts of stabilizer.
Conclusions on Polypropylene Marlex® Mesh Long-Term Stability

After looking at the amount and type of stabilizer in the Prolene® mesh we conclude that the PP is drastically under-stabilized for its intended application. Any PP part intended for many decades of use would need 20-40 fold more antioxidant. For thin PP items in aqueous environments one would need to use over 40-80 times as much antioxidant than is found in the Marlex® mesh. Furthermore, a better type of antioxidant would need to be added. Specifically, high molecular weight HALS such as Chimassorb 944 has been shown to perform dramatically better than hindered phenols alone in PP fibers exposed to water.

Looking at the Marlex® stabilization by different independent methods gives the conclusive result that the Marlex® will not survive anywhere near the required 40-60 years in the body. Using Boston Scientific’s own method, the predicted lifetime is at most 2-3 years in vivo. It will certainly oxidize, crack and fail mechanically because it was improperly formulated.
Long-term Stability of Mesh Made with China Sourced Resin

Polymer Solutions Report
Polymer Solutions were hired by the defendant’s council to analyze the antioxidants in the China sourced PP. They found that the primary antioxidant in genuine Marlex® is Irganox 3114 whereas the China Sourced Resin is stabilized using an entirely different antioxidant called Irganox 1330 (Table 3). The genuine Marlex® contained more primary antioxidant, 685ppm, compared to the China Sourced Resin which contained less than 500ppm.

<table>
<thead>
<tr>
<th>Stabilizer Type</th>
<th>Antioxidant Concentration in Sample (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US Marlex 1</td>
</tr>
<tr>
<td>2,4-Di-tert-butylphenol</td>
<td>ND</td>
</tr>
<tr>
<td>Irganox 3114</td>
<td>685</td>
</tr>
<tr>
<td>Irganox 1330</td>
<td>ND</td>
</tr>
<tr>
<td>Irgafos 168 (non-oxidized)</td>
<td>663</td>
</tr>
</tbody>
</table>

Table 3 Antioxidant Types and Amounts for US Marlex® and China Sourced Resin

The different types and amounts of antioxidant are extremely important. They prove that the China Sourced Resin is not Marlex® HGX-030-01.

Furthermore, there is a high probability that mesh made with China Sourced Resin will fail earlier because there is significantly less primary antioxidant and 10-fold less process stabilizer in the pellets.
Figure 8 The chemical structures of Irganox 3114 in genuine Marlex® HGX-030-01 and Irganox 1330 in the China Sourced Resin

<table>
<thead>
<tr>
<th>Stabilizer Type</th>
<th>US Marlex Mesh G</th>
<th>Chinese Mesh E</th>
<th>Chinese Mesh F</th>
<th>Chinese Mesh H</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,4-Di-tert-butylphenol</td>
<td>ND</td>
<td>39</td>
<td>37</td>
<td>ND</td>
</tr>
<tr>
<td>Irganox 3114</td>
<td>106</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Irganox 1330</td>
<td>ND</td>
<td>92</td>
<td>133</td>
<td>55</td>
</tr>
<tr>
<td>Irgafos 168 (non-oxidized)</td>
<td>86</td>
<td>11</td>
<td>18</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 4 Analysis of the antioxidant types and amounts in the mesh to protect the PP in the body

Polymer Solutions also measured the antioxidants in the finished mesh (Table 4). It is worth considering those because they show how much antioxidant is actually left in the PP after some is used up protecting the polymer during high temperature processing. A startling finding is that the finished mesh made from China Sourced Resin contains just 55-133 ppm of hindered phenolic antioxidant.
That is approximately 60-150 times too little to protect the fiber for decades. That level of antioxidant is what one would expect to find in a disposable PP article, such as a drinking cup.

**Stabilization Technologies LLC Analysis Report of Genuine American Marlex® and China Sourced Resin**

Stabilization Technologies LLC was asked to analyze the PP raw material, supplied as small pellets as well as the fibers and mesh.

Firstly, we look at the antioxidants in the American Marlex® HGX-030-01 pellets (Table 5) compared to the China Sourced Resin (Table 6).

<table>
<thead>
<tr>
<th>Chemical</th>
<th>American Pellets 1-A (average of 3, ppm)</th>
<th>American Pellets 2-B (average of 2, ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irganox 1330</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Irganox 3114</td>
<td>553</td>
<td>574</td>
</tr>
<tr>
<td>Irgafos 168</td>
<td>901</td>
<td>902</td>
</tr>
<tr>
<td>2,4 DTBP</td>
<td>Not detected</td>
<td>Not detected</td>
</tr>
<tr>
<td>Ash residue (%)</td>
<td>0.001</td>
<td>0.028</td>
</tr>
</tbody>
</table>

*Table 5 Analysis of antioxidants and impurities in American Marlex® HGX-030-01.*

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Chinese Pellets 1-39 (average of 2, ppm)</th>
<th>Chinese Pellets 2-41 (average of 2, ppm)</th>
<th>Chinese Pellets 3-43 (average of 2, ppm)</th>
<th>Chinese Pellets 4-In (average of 2, ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irganox 1330</td>
<td>383</td>
<td>372</td>
<td>363</td>
<td>408</td>
</tr>
<tr>
<td>Irganox 3114</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Irgafos 168</td>
<td>68</td>
<td>68</td>
<td>71</td>
<td>28</td>
</tr>
<tr>
<td>2,4 DTBP</td>
<td>237</td>
<td>202</td>
<td>202</td>
<td>208</td>
</tr>
<tr>
<td>Ash residue (%)</td>
<td>0.026</td>
<td>0.027</td>
<td>0.032</td>
<td>0.015</td>
</tr>
</tbody>
</table>

*Table 6 Analysis of antioxidants and impurities in American Marlex® HGX-030-01.*

These results confirm the findings of the Polymer Solutions report, namely that the China Sourced Resin contains dramatically less Irgafos 168 process stabilizer and significantly less Irganox long-term stabilizer. This, combined with the impurities in the China Sourced Resin and the higher concentration of titanium catalyst residue suggests that the China Sourced Resin is likely to degrade even faster than the original mesh made from American Marlex® HGX-030-01.
Oven ageing tests are underway to test the stability of the China sourced PP compared to real Marlex HGX-030-01. Preliminary results are shown although testing is still underway (Table 7).

<table>
<thead>
<tr>
<th>Mesh Type</th>
<th>150°C</th>
<th>130°C</th>
<th>110°C</th>
<th>80°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Marlex Mesh 1690</td>
<td>&lt;45</td>
<td>&lt;240</td>
<td>&lt;1416</td>
<td>---</td>
</tr>
<tr>
<td>Chinese Mesh 2294</td>
<td>&lt;66</td>
<td>&lt;288</td>
<td>&lt;908</td>
<td>---</td>
</tr>
<tr>
<td>Chinese Mesh 2651</td>
<td>&lt;64</td>
<td>&lt;288</td>
<td>&lt;984</td>
<td>---</td>
</tr>
<tr>
<td>Chinese Mesh 2702</td>
<td>&lt;64</td>
<td>&lt;288</td>
<td>&lt;984</td>
<td>---</td>
</tr>
</tbody>
</table>

Table 7 Oven ageing results for mesh at different temperatures

The China sources mesh shows longer times to failure at 150°C but at lower temperatures, closer to body temperature, the US PP performs significantly better. This is because the Irganox 3114 in the HGX-030-01 is more effective than the Irganox 1330 in the China sourced PP. This proves the folly of relying on OIT data as Boston did. They said that the China sourced PP is more stable because of one OIT measurement at 200°C. Now we see that is not the case. The data at 80°C will be more meaningful as it is even closer to body temperature. The experiments ageing in hot water will be even more meaningful because they closely mimic body conditions.
Other companies making mesh are also aware that the product has a shelf-life. For example, FEG Textiltechnik submitted a 510(k) for their PP mesh and stated:

“The product has a stated shelf-life of 3 years which is supported by real-time testing.”

Note that they did actual testing to verify the shelf-life. There is no evidence that Boston Scientific did any such testing. They admit that they assigned an arbitrary shelf-life of 10 years to the Marlex PP pellets. They later changed that to 20 years without any testing. More recently, they changed their shelf-life again. This shows an alarming lack of professionalism.

That means that they have no idea how much antioxidant is protecting the mesh when it is implanted. In a letter to DEKRA dated February 2nd 2016 Sean Curran PhD, Senior R&D Fellow at Boston Scientific stated:

“Antioxidants and sacrificial stabilizers utilized in the production of Marlex HGX-030-01 and other polypropylenes, in other words, antioxidants are consumed over time.”

This means that they acknowledge that the antioxidant is being consumed. The fact that they pay no attention to the consumption of antioxidant once the mesh is implanted it a glaring omission.

In a memo dated August 11th 2016, Sean Curran stated:

Email Curran to Burrill 06.02.16 says based on the high impact PP strands paper that:

“Given the lifetime at 80°C, I calculate an RT lifetime of 40-60 years”

Where “RT” is a chemists’ abbreviation for room temperature. This statement is deeply troubling. He is saying that he believes the room temperature stability of the PP to be 40-60 years. If this is implanted in a 20 year old who lives to be 100 years old, then the PP mesh is required to be stable for 80 years. Moreover, inside the body the PP is exposed to temperatures well above room temperature and under harsh oxidative conditions. This shows that the PP mesh is not stable enough and that Boston Scientific had all the information to realize that.
That is damning enough but a closer look at that article reveals the problem is far worse. Curran has calculated the 40-60 years based on PP samples immersed in water at 80°C. The estimation is fairly accurate based on the data in that article. However, it does not apply to Marlex®. The samples in the article Ba and Cb contain over 4000-5000ppm of hindered phenol. Marlex® mesh contains just 100ppm according to their own analysis by Polymer Solutions. Using Curran’s own method, based on the results from this article, we would predict a stability for Marlex® of 40-60 years x (100ppm/4000ppm) = 1 to 1.5 years in water. The predicted lifetime of the PP would be even less in the oxidizing environment in the body.

**Boston Scientific’s own results and reasoning predict approximately under 2 years of life for Marlex® in the body.**

Often companies buy an off the shelf, commodity PP and use it for an application for which it was not designed. For example, Marlex HGX-030-01 was designed for rope, carpet backing and other non-demanding applications. In such instances, it is common to add stabilizers, as Ethicon did, to provide additional performance to meet the intended use. It is normal practice to ask the stabilizer suppliers for formulation suggestions and even testing to ensure sufficient stabilization. For example, when exposure to rain or water is expected, Atlas Weather-Ometer® are machines designed to mimic those conditions.

Boston Scientific made no attempt to formulate the PP to meet the extreme demands on implanted mesh which must last decades in an oxidizing environment. They did not consult with the stabilizer suppliers or external consultants. They could have put in additional antioxidant during fiber manufacture chose not to. Nor did they measure the antioxidant concentration at any stage in the process or make a credible attempt to determine whether enough was present and whether the right type was present in the Marlex HGX-030-01. These are all standard procedures that would have been used by any company wanting to ensure the long-term durability and fitness of their product in use. That applies to household appliance companies and automotive companies but especially to medical device manufacturers.
Conclusions

It has been shown using different methods that Boston Scientific’s pelvic floor mesh made using genuine Marlex HGX-030-01 contains far too little antioxidant to protect the PP for decades in the body. The mesh would need to contain 40-80 times more antioxidant to have any chance of surviving for the required time-period. Furthermore, an essential type of antioxidant that resists extraction into water has not been included. Thus, the type and amount of antioxidant are both incorrect. The type and amount of stabilizer is what would be expected for a common disposable PP item like a disposable drinking cup. It is totally unsuitable for long-term use.

The China Sourced Resin being implanted now is counterfeit Marlex® as shown by forensic analysis of the pellets and the mesh by Boston Scientific’s own contract labs and the more detailed analysis performed by Stabilization technologies, LLC. The China Sourced Resin used a completely different type and amount of antioxidant as well as several impurities. The process stabilizer is present at concentrations one tenth that of genuine Marlex® HGX-030-01. The long term hindered phenol stabilizer is also present at a lower concentration than used in genuine Marlex fiber mesh which may lead to decreased stability of the mesh. In conclusion, we can state that while the original Marlex® HGX-030-01 based mesh was dramatically under-stabilized, the China Sourced Resin being used now is even worse.
Recent Testimony – Chris DeArmitt PhD FRSC CChem

Deposition / trial testimony: None
Appendix A - Curriculum Vitae for Chris DeArmitt

Conference Chairing and Organizing
Polymer Degradation & Stabilisation Conference (Sweden 1999) – Organizer
High Performance Plastics, RAPRA, Cologne (Germany 2011) – Organizer

Presentations
Conference in Mineral Processing (1999)
Macromolecules ‘99
Engineering Thermoplastics (2004)
Cosmeceuticals Summit 2008
AddCon 2008
Nanopolymers (2008, 2009)
NPE/Antec (2009)
Advanced Materials Symposium (2009)
Smart Polymer Systems (2010)
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)


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


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


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


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

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


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: 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.


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


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
References

1 See BSCM05600022969.
17 Zweifel, Plastics Additives Handbook, at page 34.
19 ISO 4577 Polypropylene and propylene-copolymers -- Determination of thermal oxidative stability in air -- Oven method.
21 ASTM D5721 Air-Oven Aging of Polyolefin Geomembranes.


39 BSCM04500000465

62 Polymer Solutions report dated April 25th 2016
63 FEG Textiltechnik, DynaMesh-PP (Standard and Light) 510(k) Summary letter August 1st 2008.