HAEMONETICS®

Haemonetics Statement on the Safety of Our Blood and Plasma Collection Devices
July 2, 2020

A consortium of newspapers has published stories that attempt to raise questions about our products and imply a pattern of behavior about how we approach safety issues concerning our devices. The stories are all basically the same: they tie together pieces of information, comments taken out of context and isolated matters that have been resolved to draw false and misleading conclusions.

We are confident that any balanced, fair and accurate assessment of our decades long record in safe blood component collection and our commitment to investigating and resolving any matter pertaining to the quality and safety of our products would present an entirely different picture of our company.

The articles make an array of claims that are erroneous, without foundation, leave out critical information, and suggest that the use of our products in the collection of plasma and blood may be unsafe. Nothing could be further from the truth. Our customers and donors around the world absolutely can and should feel confident in the safety of our products used during the collection process.

While we provide more detail below, we want to underscore a few key points that we believe clearly demonstrate that the premise and the conclusions of the articles are without merit:

- There is no evidence of donor, patient or user harm associated with the use of our products in the reports cited in the stories.
- No Haemonetics machines were ever banned as a result of the matters discussed in the articles.
- Over a 15-year period, total particle related complaints represent an extremely small fraction of a percent of total plasma collection procedures.
- As with every medical device and even in drugs that are specifically meant to be injected into the body, the presence of particles cannot ever be reduced to zero. Our product design, our manufacturing process and the procedures followed by our customers in the use of our products aim to minimize the occurrence of particles as much as possible to continuously ensure the safety of donors, patients and the customers who use our devices.
- Our devices are made from biocompatible materials and tested according to stringent international standards to ensure that they are not toxic to the human body.
- Contrary to what has been stated in these articles, our blood and plasma disposable kits contain no metal in the rotating seal or elsewhere. The rotating seal is formed from a combination of biocompatible carbon and ceramic components.
- We work transparently with regulators to manage and resolve issues that arise.
- We manage a stringent quality system that ensures strong post-market surveillance of our products to ensure their safety and effectiveness and we rigorously comply with all laws and regulations in the markets where we operate.

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Statement

Haemonetics' blood and plasma collection devices and disposables have been used worldwide for decades to safely and effectively collect plasma, platelets and other blood components. In the past 15 years alone, our products have been used safely in more than 360 million plasma collection procedures globally. We do business in over 85 countries and comply with all local

laws and regulations covering our operations and products. The safety of Haemonetics' products for donors, patients and users has always been and will remain our top priority. The global need for plasma and plasma-derived medicines is well-documented and increasing and it is important that donors and patients alike understand the long track record of safety around these and other blood component collections, so that the life-saving treatments and therapies derived from them can continue.

Recent assertions about disposable kits used with our machines in different countries are unfounded and erroneously suggest that the collection of plasma and blood may be unsafe. Nothing could be further from the truth. Our products are safe and used daily in more than 100,000 blood component collections worldwide, including vital efforts to collect plasma for life-saving drugs and therapies, as well as to support early-stage research for the treatment of COVID-19.

Most of these assertions stem from questions raised in 2018 about particles that appeared in a single plasma disposable kit (782HS-P-SL) used by one of our customers in France. That issue also has been thoroughly reviewed by the French health authority, The National Agency for the Safety of Medicines and Health Products (ANSM), which, as a precautionary measure, suspended use of the kit. ***No machines were ever banned.*** Our devices continue to be used in France with other disposable kits to collect blood components, including plasma. The ANSM has subsequently affirmed that the particles observed were organic in origin, likely coagulated blood, and that there were no reported injuries or proven risks to donors, patients or users. The French National Blood Service (EFS) also confirmed there were no health issues for donors, patients or users resulting from the kit.

In January 2019, the ANSM reiterated that there is no proven risk to donors or patients and lifted the ban on the use of therapeutic plasma that had been collected with Haemonetics' 782HS-P-SL disposable kits. We hosted members from the ANSM at our state-of-the-art manufacturing facility to evaluate our manufacturing operations first-hand. We will continue to work closely with the ANSM to fulfill any additional requests.

No other markets or customers have been affected by the suspension of the Haemonetics 782HS-P-SL disposable kit, which has a configuration unique to the French market and is not sold in other markets.

Haemonetics takes any product-related reports and related post-market surveillance duties very seriously. Other reports about our products that have been surfaced by the media recently, some of which are nearly a decade old, have also been thoroughly investigated in full, and we have transparently cooperated with and answered any questions from regulatory authorities. None of these reports have been associated with donor, patient or user harm from the use of our products.

We also want to address several other misleading assertions that have been raised by the media:

1) **Media Assertion: The company has an inordinately large number of reported "incidents."**

   The Facts: Like any medical device company, we are required to track all customer inquiries and reports related to our products and they relate to a broad range of topics. We welcome this input because it is part of our continuous improvement processes, and we review and address them all. The number of reports we receive (to describe them as "incidents" is misleading) is not unusual for a medical device company that ships tens of millions of products annually and is line with industry averages for similar kinds of

operations. The vast majority of these reports involve minor issues, including cosmetic complaints, such as scratches on a device or packaging irregularities. A small number of plasma reports involve mechanical and technical questions. Of these mechanical and technical questions, any that are health-related and medical in nature are taken very seriously with expedited review and are appropriately reported, investigated and resolved.

Particles referenced in complaints related to our plasma products were not necessarily in the collected plasma or found during product use. For example, some complaints were related to suspected particles found during inspection by the customer before the product was used and either discarded or returned. Over a 15-year period, total particle complaints represent approximately 0.0006% of estimated total plasma collection procedures.

The incidence of particles in medical products is not limited to Haemonetics' products (as small particles cannot completely be eliminated from any manufacturing process.) For example, medical literature has established the limits for the size and amount of particles that are allowed in solutions for injections and that it is deemed safe. While we ensure the highest quality of product during collection, it is also important to understand that all collected plasma is either fractionated or filtered before it is transferred to a patient or used to make medicines. Moreover, Haemonetics' disposable kits are designed to be biocompatible with their intended use for humans, meaning they have no injurious effects. We have extensively tested both the components of the kits and the finished medical devices to ensure they are safe and non-toxic for humans in strict adherence to the appropriate regulations and international standards on biocompatibility.

2) **Media Assertion: The PCS®2 and MCS®+ machines used in other countries are "part of a ban in France that was implemented in 2018."**

The Facts: The PCS®2 and MCS®+ machines have never been banned in France or anywhere else in the world.

3) **Media Assertion: Haemonetics told the media that the issues concerning particles were restricted to France and stemmed from a particular piece of a single disposable kit, but similar issues had occurred in other countries.**

The Facts: The product-related reports in France were publicly disclosed and thoroughly investigated in full and we have transparently cooperated with the authorities in France. None of these reports have been associated with donor, patient or user harm.

We also answered questions arising from the action in France from other agencies in the world, none of whom felt it necessary to take any further action in their jurisdictions.

Regarding reports of particles beyond the 2018 ANSM action in France, in 2011 there was a voluntary recall of disposable kits limited to a few European countries where black particles were found in our high-separation (HS) centrifuge bowls used in plasma collection. There were no reported injuries to donors, patients or users. At the time, we completed a thorough investigation working closely with our main impacted customers, as well as with relevant European authorities to identify the root cause. We took all the appropriate precautionary and corrective actions, and these products were subsequently reintroduced to the European market.

4) **Media Assertion: Internal emails and opinions of outside doctors/commentary demonstrate that the company has not done enough research about the health implications of smaller particles appearing in plasma donations.**

The Facts: Through both our quality system and our corporate code of conduct, we encourage our customers and require our employees to report complaints and incidents. All reports are logged and tracked in our internal reporting system, taken seriously, investigated thoroughly and addressed. The emails and comments referenced do not provide an accurate and complete picture of the company's attention to evaluating the risk profile of particles and designing our products accordingly. Portions of the emails were extracted from their proper context, tied erroneously to other information and extrapolated to mean something they do not.

As noted above in the answer to assertion #1, Haemonetics' disposable kits are designed to be biocompatible with their intended use for humans, meaning they have no injurious effects. We have extensively tested both the components of the kits and the finished medical devices to ensure they are safe and non-toxic for humans in accordance with the regulations and international standards that require this. While we ensure the highest quality of product for use during collection, it is also important to understand that all collected plasma is either fractionated or filtered before it is transferred to a patient or used to make medicines. Our devices have a proven track record over decades of safe and effective use in hundreds of millions of procedures that are a source of life-saving therapies for people around the world.

5) **Media Assertion: The use of Haemonetics' PCS®2 and MCS®+ machines in numerous countries raises questions over the potential risk to patient and donor health.**

The Facts: These devices have a proven track record, based on hundreds of millions of collections and on the work that has been performed to continuously improve collection safety and efficiency. This is further supported by the authorities in France and elsewhere having reaffirmed the safety of donating plasma, platelets and other blood components. The benefit-risk profile of using our blood component collection products is overwhelmingly positive.

It is highly unfortunate that these baseless assertions about our devices are being made at a time when, according to the Plasma Protein Therapeutics Association (PPTA), roughly 750,000 people across Europe and North America alone rely on plasma for life-saving therapies, and the need for plasma is critical and growing. Donors around the world absolutely can and should feel confident in the safety of our devices used during the collection process.

6) **Media Assertion: Haemonetics devices contain two metal rings that are part of a swivel joint implying that they are cause of traces of metal in the particles.**

The Facts: Our bowls in our disposable kits contain no metal rings – the rotating seal of the bowl is made of two components, a carbon ring and a ceramic ring. Both have been tested to ensure their biocompatibility safety and performance.

7) **Media Assertion: The donation of plasma or platelets using a Haemonetics device has been associated with an instance of cancer.**

The Facts: Haemonetics' disposable kits are designed to be biocompatible with their intended use for humans, meaning they have no injurious effects. We have extensively tested both the components of the kits and the finished medical devices to ensure they are safe and non-toxic for humans. We are not aware of any reports proving that donating plasma or platelets with *any* apheresis machine can cause cancer.

8) **Media Assertion: There was a spike in the deaths of donors who donated plasma using a PCS®2 machine in the past three years.**

The Facts: This is incorrect. In 2018, Haemonetics voluntarily changed its Medical Device Report (MDR) reporting approach to be more conservative and to align with the reporting practices of our plasma customers. At this time, Haemonetics began filing a report for *any* plasma donor fatality reported to us, regardless of whether the device may have caused or contributed to death or serious injury. This change in approach resulted in an increase in MDR reports but provided additional transparency to the U.S. Food and Drug Administration (FDA). Prior to 2018, Haemonetics did meet the regulatory requirements to complete MDR reports. Up until that time, as is standard in the industry, there was a determination made by qualified personnel on whether the event met the MDR requirements prior to reporting and only those that did were reported. Following our voluntary change in reporting approach in 2018, we have routinely reported all deaths reported to us by our plasma customers whatever the cause (such as road traffic accidents) and there were no MDRs during this period that associate any death with the use of the PCS®2 or NexSys PCS® products.

The above statement speaks only as of the last updated date indicated above, and Haemonetics does not undertake to publicly update or revise this statement.