Use of Plastic Regrind in Medical Devices

Introduction

The use of recycled plastic regrind in the production of medical devices has not met with easy acceptance, given the clear need to ensure their safety and reliability. Concerns about part performance, contamination, and increased failure modes have led the industry to opt for virgin material almost universally. However, Teel's experience using regrind for a medical customer demonstrates that with a thorough understanding of part requirements and downstream operations, engineering medical components for regrind use is possible in some cases and can offer several advantages.

Background

A long-term medical customer approached Teel about using regrind in one of their device components with the hope of reducing costs and achieving their environmental and sustainability goals. To assess the viability of regrind for the component, Teel worked closely with the customer, gathering more detailed information than typical to assess the impact of regrind use on the part's performance, failure modes, and contamination potential.

Part Performance

Information Gathering and Analysis

Teel began a process of inquiry and testing, beginning by defining the performance scope of the component to narrow down the physical attributes that should be tested and the target values for each attribute.

Teel first determined:

1. The essential function of the overall device
2. The essential function of the component to be made with regrind
3. The operations performed on the component after production at Teel
4. The risks of the device and component failing to perform as expected

The overall device was a tube-like, rigid applicator, and the function of the component in question was to eject the active portion of the device from a protective housing. Secondary operations needed after production included heat forming to fit the part to the final device during a high-speed assembly operation. Because the device component would be touched, feel and cosmetic appearance would also be important, although secondary, concerns. The component's essential function required the device to be stiff and resist both crushing and buckling. With this background, Teel was able to create an outline of the attributes that were essential to the performance of the component and could be impacted by the introduction of regrind.

Teel determined that since critical component dimensions were machine and process driven, adding regrind, if it changed the part's material properties and caused it to behave differently, could influence that process and impact the final part dimensions. One aspect that could be affected was wall thickness,

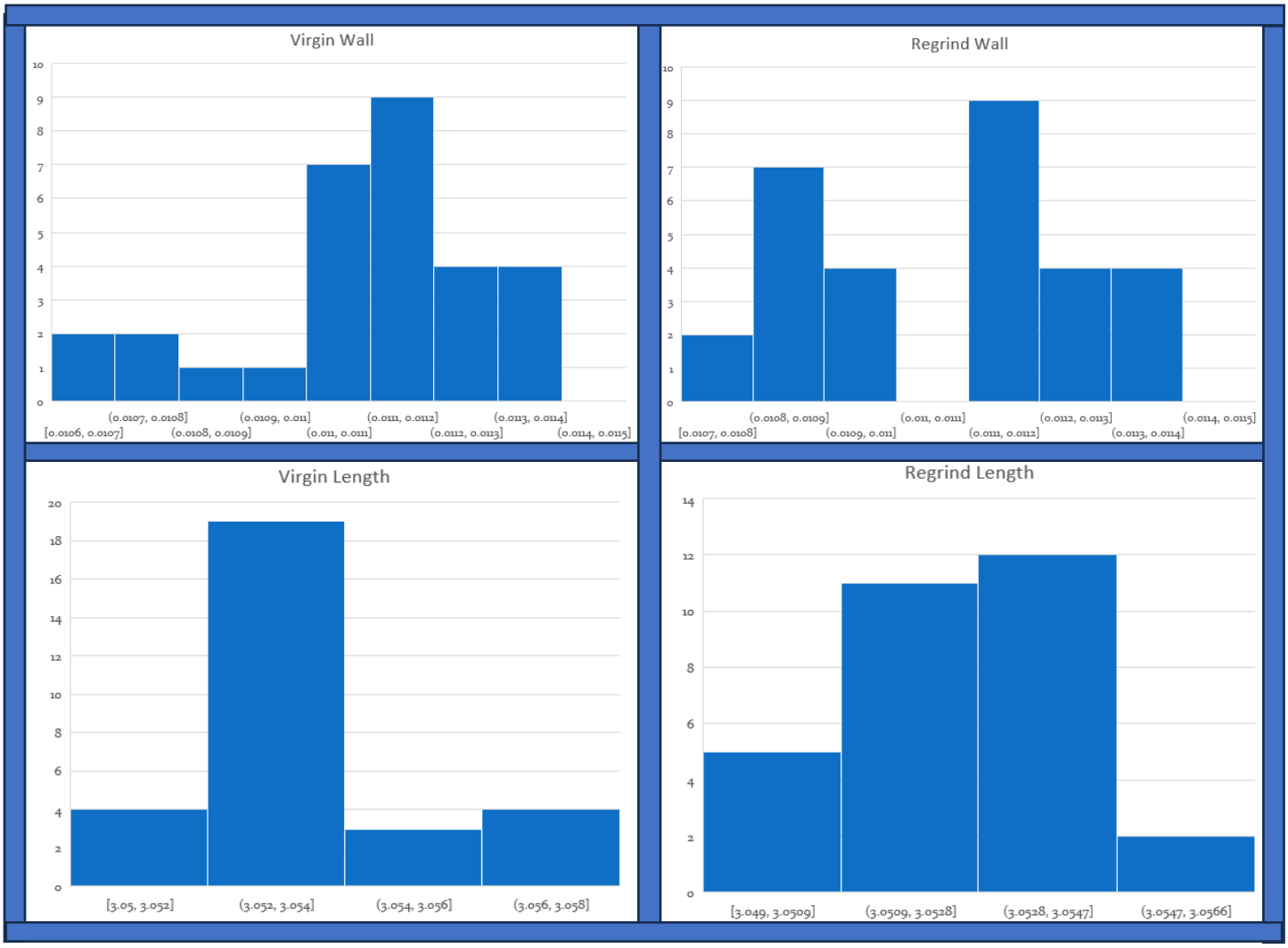
which would ultimately impact the stiffness of the component. Material and dimensional control factors, including wall balance, could also impact the component's crush resistance.

Since the forming process the customer uses involves melt temperature and degree of material melt, regrind had the potential to impact this process as well. Regrind polymer is slightly degraded and flows differently than virgin material. It can also crosslink, as well as potentially contain gel or unmelts, impacting dimensional stability. However, if the process were sufficiently in control and Cpk were high, it would still be possible for the performance to drop while remaining within acceptable dimensional tolerances and Cpk. On the other hand, Teel had previously seen some post-production processes become more stable with regrind added, possibly because the additive blended better with the material or from the addition of a small amount of higher melt index material. In any case, Teel needed to check the percent crystallinity and melting profile of the parts at the secondary operation temperature.

Further, as regrind can sometimes have a yellow or off-color tint, the cosmetics of the part could also be impacted and would need to be examined.

Test Results

Teel Analytical Lab ran a series of tests, detailed below, on virgin component samples and samples with regrind introduced, comparing their dimensions, crush resistance, melt flow, and appearance. The test results indicated a similar dimensional control for virgin and regrind components. Wall thickness showed a Cpk of 3.04 with regrind and 2.97 with virgin material. Length control showed a Cpk of 1.36 when using regrind and 1.52 when using virgin.



Dimensional test results

As for crush resistance, the customer set a column strength minimum of 10 lbs., and as shown below, the results were well above that range with both virgin and regrind. The average was slightly higher with regrind, which was potentially the result of wall size differences.

Sample	Replicate	Column Strength (lbs)
Applicator Virgin	1	17.74
	2	17.36
	3	17.82
	4	18.50
	5	18.20
	Average	17.92
	Std	0.44
	%RSD	2.45
Applicator Regrind	1	18.94
	2	18.28
	3	17.86
	4	18.02
	5	18.28
	Average	18.28
	Std	0.41
	%RSD	2.26

Crush resistance test results

DSC results showed regrind had no issues melting at the approximately 120°C the customer used in its secondary forming operation before assembly. As shown below, the tightness of the first and second heat melting indicated the low degradation for the regrind part.

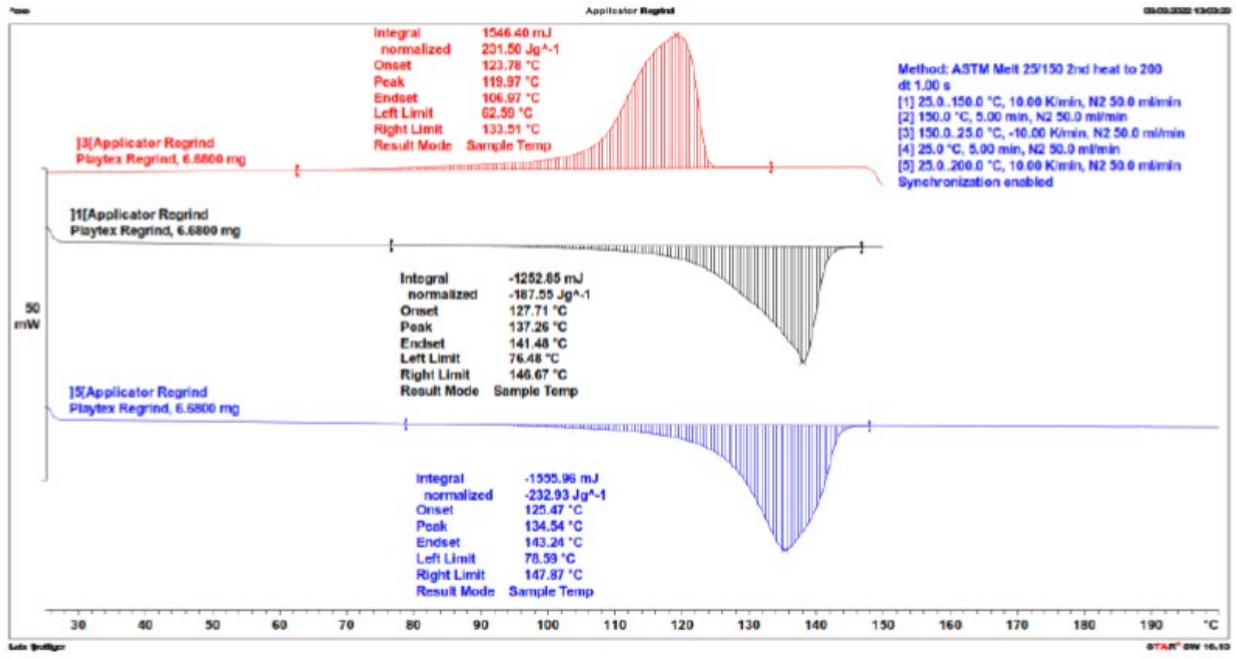


Table 1. DSC Sample Results

	Thermal Event (First Heat)			Thermal Event (Second Heat)		
Sample Name	Onset (°C)	Enthalpy (J/g)	Melt Peak (°C)	Onset (°C)	Enthaly (J/g)	Melt Peak (°C)
Applicator Virgin	127.70	-186.83	136.63	125.31	-233.45	134.47
Applicator Regrind	127.71	-187.55	137.26	125.47	-232.93	134.54

Melt flow test results

Contamination

When considering the effects of regrind on part contamination levels, it is important to note the risk profile is dramatically different for different types of devices. In addition, the profile will always be higher when once-processed and ground materials are used.

To create a risk profile for the customer, Teel considered the product's life cycle and assessed two main categories of contamination potential from adding regrind.

The first category included known and expected sources of part contamination. In this case, the known sources would be machine debris, degraded material, resin packaging, regrind packaging, and cardboard.

The second category of contamination risk includes unknown sources, which are either entirely unexpected or are potentially foreseeable but cannot be prevented by any engineering controls. In this case, the presence of other polymers in the regrind fell into the latter category and would be the key area of risk in the introduction of regrind. Teel engineered a closed-loop solution minimizing both of these risks by dedicating grinders solely for the regrind material used in the component.

Failure Modes

To assess the impact of regrind on the part's failure modes, Teel conducted an analysis of the component's typical and hypothetical failure modes and the potential impact of regrind on each.

Typical failure modes were determined to include buckling and collapsing, both the result of the part's thickness and material attributes. These failure mode risks could be addressed by developing an engineering requirement.

Hypothetical failures modes were determined to include failure to form during the customer's post-production process, material on the inner diameter of the part, and splitting. Two of these failure modes were observed during the customer's forming process, but were not serious and caused no patient risk. First, splitting in the wall occurred, and a root cause analysis showed contamination to be the cause. This was later minimized through manufacturing controls as described above. In addition, the customer noticed uneven forming during the process. The root cause was determined to be uneven wall distribution, and while the slightly worse Cpk values with regrind indicate this failure could be more frequent with regrind parts than virgin, the defect created was only visual. As with the first failure, it created no patient risk.

Benefits to Customer

In the end, up to 25% regrind was qualified to be added to this customer's product, as the regrind only minimally increased the part's failure risk during their operations and that posed no increased risk to patients. The use of regrind reduced the material sent to the landfill over the course of making this product by approximately 110,000 lbs. The customer also saw significant cost savings eliminating the need to price in the cost of scrap material.

Conclusion

This case study shows that having accurate and specific engineering information on part requirements and downstream operations is necessary to assess how regrind will impact a part's performance, failure modes, and contamination risk. Regrind may not be right for every medical device, but it does have the potential to reduce waste and cut costs without negatively impacting performance. Undertaking the detailed analysis required to find out can be worth it.