

Guide to Minimizing Damage to Surgical Sharps During Manufacturing and Assembly

Much has been written by organizations such as the CDC and OSHA concerning the handling techniques needed to properly handle surgical sharps during use. This information is 100% focused on preventing injury to healthcare professionals and patients. In other words, **the focus has been on what sharps can do to people when improperly handled.**

IncisionTech is the leading provider of custom surgical sharps for medical device OEMs. As the **Center Of Excellence** for incisional devices our core competence is providing expert solutions for surgical cutting, piercing, and delivery. Our goal is simple - To enable better patient outcomes through innovative incision technologies. In order to enable better patient outcomes we focus on assuring the highest quality products get to the ultimate patient. This means we must focus our efforts on **what people can do to sharps during manufacturing and assembly.**

Some common issues relating to poor functional cutting and piercing performance in the field are a direct result of damage caused to the components during manufacturing and final assembly. These issues can be minimized by incorporating the following guidelines:

- First understanding that any material that comes in contact with cutting blade edges or needle tips has the strong potential to damage the component. For this reason all processes following cutting edge or needle tip generation should be designed and executed in a way that prevents any contact with other materials or surfaces.
- Inspection techniques need to incorporate non-contact measurement means. This eliminates any potential for hardened measurement tools (such as calipers or micrometers) coming in direct contact with the fragile features.
- Tooling used to locate sharps during subsequent laserwelding, overmolding, forming, or cleaning processes needs to provide large areas of relief for sharpened edges or needle tips to assure no contact is made in these areas.
- Work instructions for loading and unloading laserwelding, overmolding, forming, or cleaning tooling need to highlight the importance of protecting the cutting edges or needle tips. Let it drop - Never catch a falling sharp component. Also, if a part is dropped or inadvertently comes in contact with any other surface it should be scrapped or re-inspected for goodness prior to use.
- All material handling carriers and trays should be designed and manufactured in a way that fully secures the product and prevents any contact with sharpened edges or needle tips. Care should also be taken to fully contain the cutting blade edges or needle tips within the carrier or tray so as not to open up the potential for any incidental damage due to exposed areas.
- Many coating and electropolishing processes also have high potential for damage when performed on sharp components. Coating thickness buildup along sharpened edges or needle tips increases ultimate radius of curvature (and reduces ultimate sharpness). Electropolishing can also round sharpened edges or needle tips and have a similar effect on sharpness reduction.
- Work instructions for final assembly also need to highlight the importance of maintaining the integrity of the sharpened edges or needle tips. If parts are dropped or inadvertently come in contact with any other surface they should be scrapped or re-inspected for goodness prior to use. Operators should also look for any obvious component damage under good light and low magnification (~5X).
- Final packaging should also be designed and manufactured in a way that prevents any contact with cutting edges or needle tips. Protective caps and soft foam can also be used as additional means of extra protection.

For more information on how we can help you assure the best outcome in your device call us at 800-213-7809