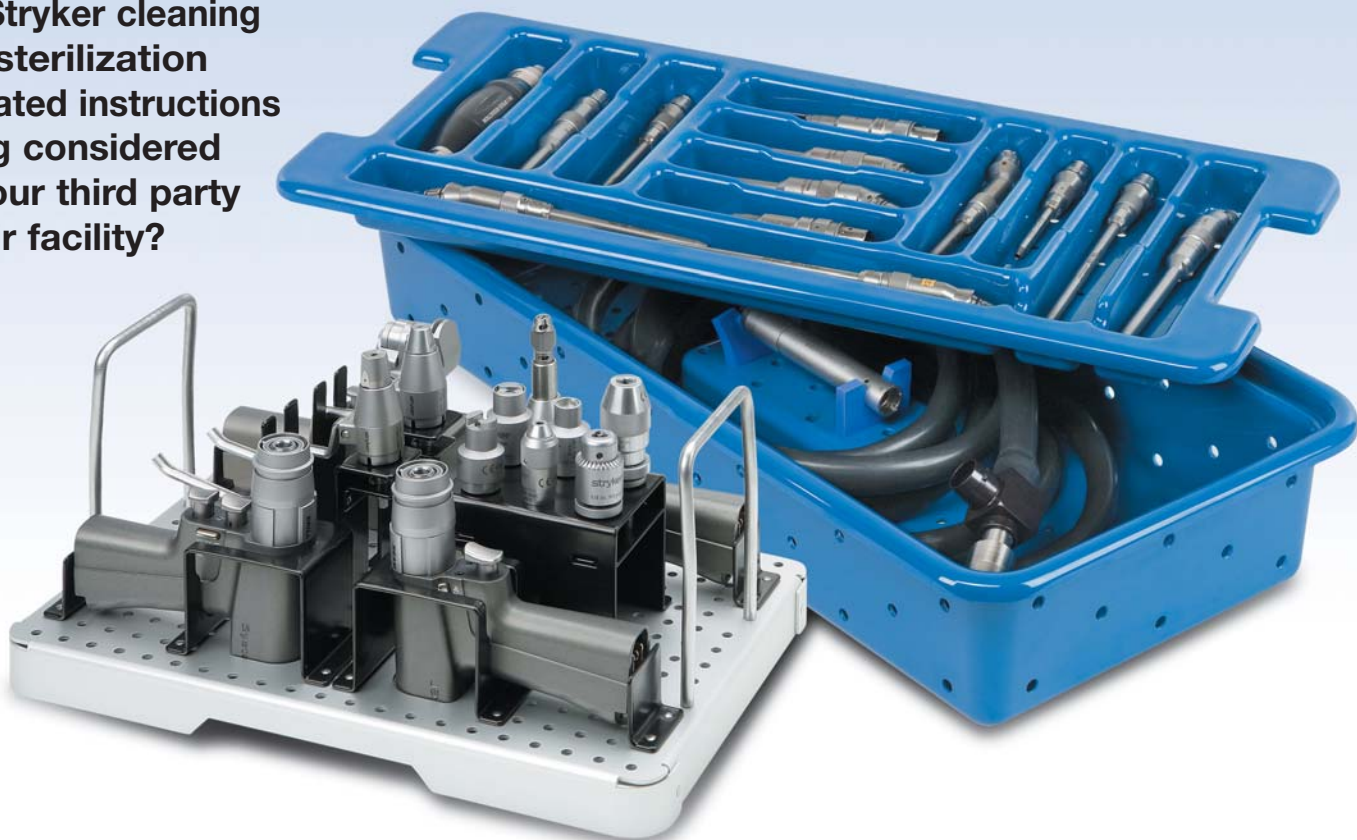


You know better than anyone how difficult it is to clean and sterilize your equipment.

**Are Stryker cleaning and sterilization validated instructions being considered by your third party repair facility?**



Third party repairs may not be backed with cleaning and sterilization validation. Stryker stands behind every repair with the same validated specifications we provide with brand new equipment.

**Equipment repaired at a third party repair facility may have compromised:**

- **Electrical approvals**
- **Seal integrity**
- **Performance**
- **Functionality**
- **Reliability**
- **Longevity**



**Fixed right the first time.  
Proceed with confidence.**

**stryker®**

# It says Stryker on the outside...but is it?

**A device repaired by a 3rd party is just as good as new, right? We don't think so.**

## Why are Cleaning and Sterilization Validations important?

- FDA requires manufacturers to perform cleaning and sterilization validation per the Quality System Regulation 21 CFR Part 820 for process controls.
- Stryker Power Tool Systems are verified by testing as outlined by the AAMI Standards for cleaning effectiveness, when adhered to, ensure the removal of contamination.
- During a repair at Stryker, each device is disassembled and reassembled per a validated process, ensuring the original validation is not impacted
- **"If it isn't clean it can't be sterilized"**. Validations on reusable devices ensure instructions for cleaning can be relied upon with sterilization to return a safe product to the operating room. In addition, if a device is serviced outside of Stryker's specifications, we cannot guarantee the level of cleanliness.

## Can your repair facility provide proof of proper validations?



Stryker Power Tool systems are in full compliance and carry the Canadian Standards Association (CSA) safety mark for electrical Medical Devices.

**It is important to note that once a Stryker Power Tool is repaired using non-Stryker components these safety marks are nullified.**

## Can your repair facility provide proof of compliance?

## Why are Electrical Approvals important?

- The FDA requires safety performance testing. IEC 60601-1 is the recognized standard for medical electrical equipment.
- In conjunction with FDA requirements, a number of states require medical devices to carry a valid safety agency mark for use in local hospitals and clinics.
- Nearly all hospitals and clinics in the US require safety marks on equipment to be purchased.



**Example of a burned out 3rd party motor controller.**

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