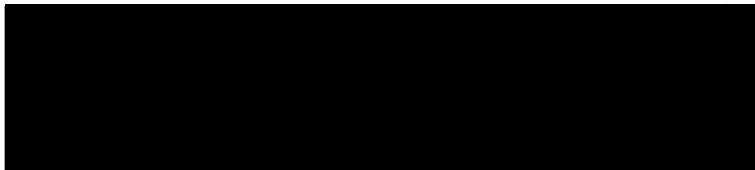

DATE: 3/16/2017
TO: Field Investigation 655686
FROM: Alex Aten, Product Development Engineer
RE: 398.960 Length Labelling Error

The label for the Stagbeetle Forceps (398.960) incorrectly listed the overall length of the part as 120mm instead of 125mm. This error was corrected on DCO_090029, but there is still product in the field with the incorrect label.

For parts in the field prior to the label being corrected, the error does not impact the safety or efficacy of the forceps. The parts were manufactured correctly to the specifications on the drawing, only the label listed in the incorrect overall length. The length on the label is not used to distinguish the forceps from any other parts or to determine which forceps to use in surgery. There are no alternative stagbeetle forceps that the 125mm forceps would get mixed up with. Additionally, the parts are sold non-sterile and the label would be discarded before the parts are used. A review of the complaint history found no complaints for these parts, confirming that the labeling error has not caused issues intraoperatively.

The incorrect label will not have an adverse impact on the performance or safety of the device; therefore the forceps are acceptable for use.



Alex Aten, Product Development Engineer