

## **Microstim Packaging**

The only way to test packaging is to send a package and examine upon return. This was done and then instruments were sent out and returns (0) monitored. With many thousands now having been shipped without mishap or complaint, the data is zero failures in packaging. This can be proven by access to the Viamed QA system records.

Due to ecological pressure in 1995 the Microstim was packaged in ecological friendly materials. However, the user prefers instruments that are packaged to look like everyday items they buy and use.

ISO9001:2015 “minimise the risk of customer satisfaction “which sits nicely with ISO13485:2016 products should be “safe and effective” The current packaging also adds protection in transit by the user. Council Directive 1993L0042-EN-11.10.2007-1 Annex 1 Essential Requirements 1. General Requirements 5

The original Microstim was designed to be carried, and purchased privately by clinicians, usually anaesthetists moving between locations. In most cases they were carried in pockets. Hospitals now purchase these units and they stay on trolleys etc. and are therefore more likely to be stacked then dropped, hence the carrying case.

### **Validation**

Instruments have survived the post and courier tests.

Many (in excess of 4,600 Pt. No. 250000 2001 -2006 ) (564 Pt. No. DB1000 to Jan 2001) (approx 1400 1986 – 2001) have been shipped world-wide without damage.

These figures should validate all the packaging used.

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