

7.0 PACKAGE QUALIFICATION, LABELS / INSTRUCTIONS FOR USE

7.1 Physical Package Qualification

Elastomeric Chain and ligature thread devices are packaged in spools or plastic boxes for ligatures as determined for the product.

Each spool is packaging in a plastic pouch resistant against UV

These devices must be kept clean, but as elastomeric devices are not likely to be damaged or spoiled during shipment and are small, lightweight items, the packaging for these was qualified by design with no tests run.

The packaging for elastic devices has been used since their introduction into the market.

7.2 Labels

7.2.1 General:

Packaging for Elastomeric Chain, elastomeric rings and thread devices is with labelling information instructions Graphical symbols per EN ISO 15223-1 are used when applicable symbols are identified.

Barcode, printed on the label of external UV protection pouch (secondary packaging) contains Lot, product part number, expiration date (Best Before: Month Year), and quantity. This information is also available in text on the same label.

Directly on the spool (primary packaging) are printed product part number, Lot number and when applicable symbols

7.2.2 Example of elastomeric chain / ligature thread in spool labels

Primary Packaging:



Secondary Packaging:



