Definitions

Implants referred to in this fact sheet include, but are not limited to: screws, hooks, rods, plates, cages, discs, washers, nuts and associated spinal, trauma and CMF implants. These are owned by the facility or they may be delivered to the facility via a loan set or on consignment.

Screw banks are sets of orthopaedic screws of various sizes and types presented in a screw caddy. Many facilities are now replacing these systems with ‘sterile single packaged items’.

All implants are single-use medical devices. Some single-use devices (SUD) are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.

Once the sterilized set of implants is opened in the operating suite, the unused implants within the set are regarded as ‘opened but unused single-use medical devices’. ‘Opened but unused’ is the term used to refer to a SUD whose packaging has been opened but the device was not used and did not come in contact with blood, tissue or bodily fluids\(^1\). The TGA regards ‘opened but unused’ as having the same meaning as packaging that is damaged\(^1\).

The subsequent re-sterilization of the unused implants must be undertaken in accordance with the manufacturer’s instructions. The intended use for the device has not been changed, there is no reuse occurring and the reprocessing and re-sterilization is in accordance with the manufacturer’s original instructions.

However, if one of these single use devices is used or comes into contact with blood, tissue, or bodily fluids, the device is taken to be used and cannot be remanufactured for reuse on another person unless the remanufacturing is undertaken in a TGA-certified manufacturing facility\(^1\) (which does not include Queensland Health sterilizing departments).

**Any reprocessing must be performed in accordance with the manufacturer’s written instructions.**

Implants Purchased Non-sterile

- It is common practice for manufacturers to supply orthopaedic implants for restocking implant sets prior to sterilization for use in orthopaedic procedures.

- The manufacturer provides instructions on how to process and sterilize these implants prior to use and although they are only intended to be used once, those unused implants have been designed and manufactured to undergo re-sterilization in accordance with the manufacturer’s instructions.

- The regulation of the remanufacture of single-use devices does not include those single-use devices that are opened but unused\(^1\). Therefore, restocking screw bank sets with non-sterile replacements prior to sterilization for use in surgical procedures, and the subsequent reprocessing of the unused screws in these sets, are not regulated as manufacturing activities by the TGA.

Sterile Single Packaged Items

- Sterile sets of implants (screws) opened in the operating rooms but unused are regarded as ‘opened but unused single-use medical devices’\(^1\).
• ‘Open but unused’ items that have not come into contact with blood, tissue, or bodily fluids may be reprocessed according to the manufacturer’s instructions¹. The intended purpose of use for the device has not been changed, therefore no reuse is occurring.
• The reprocessing of expired stock is only to occur with written instructions from the manufacturer.

References