

25th September 2024

**RECOMMENDED PRODUCT FAMILIES FOR USE IN PROCEDURE/CUSTOM KITS AND TRAYS**

The following product families are recommended for use in procedure/custom kits and trays:

PRODUCT FAMILY	PRODUCT REF PREFIX CODE	GAMMA	ETO
<b>STERILE CARBON STEEL SURGICAL BLADES</b> Unit Pack Metal foil packet	02	Suitable	Suitable*
<b>STERILE STAINLESS STEEL SURGICAL BLADES</b> Unit Pack Metal foil packets	03	Suitable	Suitable*
<b>STERILE FINE/MAJOR/CYGNETIC/PD/MYRINGOTOMY/SKIN GRAFT (EXCLUDING 9940) SURGICAL BLADES</b> Unit Pack Metal foil packets	59, 07, 53, 58, 2102, 2201, 2203	Suitable	Suitable*
<b>STERILE STITCH CUTTERS</b> Unit Pack Metal foil packets	04	Suitable	Suitable*
<b>NON-STERILE DISPOSABLE SCALPEL WITH GUARD</b> Unwrapped Bulk Packed	23	Suitable	Suitable
<b>NON-STERILE DISPOSABLE SCALPEL WITH RETRACTING GUARD</b> Unwrapped Bulk Packed	35	Not suitable	Suitable
<b>NON-STERILE RETRACTABLE SCALPEL</b> Unwrapped Bulk Packed	40	Suitable	Suitable
<b>NON-STERILE KLEEN BLADE MANAGEMENT SYSTEM</b> Unwrapped Bulk Packed	56	Suitable	Suitable
<b>NON-STERILE BLADE REMOVER</b> Unwrapped Bulk Packed	5503 5505	Suitable	Suitable

\*Due to the pressures changes involved during EtO sterilization the seal on the foil packet may weaken as a result. Procedure Kit and Tray manufacturers are required to follow Article 22 of (EU) MDR 2017/745

The following product families can be included as part of a Procedure/Custom Kit or Tray however sterilization via EtO process may compromise the product packaging.

<b>STERILE DISPOSABLE SCALPEL</b> Unit Pack clear film & tray	05	Suitable	Due to the pressure changes involved the packet seal may become weak. The scalpel may also move and puncture the packet
<b>STERILE DISPOSABLE SCALPEL WITH RETRACTING GUARD</b> Unit Pack paper & clear film	36	Not suitable	Suitable (depending on parameters used). Due to the pressure involved in this process the packet seal may be breached
<b>STERILE RETRACTABLE SCALPEL/ STERILE KLEEN BLADE MANAGEMENT SYSTEM</b> Unit Pack paper & clear film	39, 49 57	Suitable	Suitable (depending on parameters used). Due to the pressure involved in this process the packet seal may be breached
<b>STERILE SKIN GRAFT 158mm SURGICAL BLADE -</b> Unit pack paper & clear film	9940	Suitable	Suitable (depending on parameters used). Due to the pressure involved in this process the packet seal may be breached
<b>STERILE BLADE REMOVER</b> Unit pack paper & clear film	5502	Suitable	Due to the pressure involved in this process the packet seal may be breached
<b>STERILE DISPOSABLE SCALPEL WITH GUARD</b> Unit Pack paper & clear film	66	Suitable	Due to the pressure involved in this process the packet seal may be breached

Steam Autoclave is not recommended for any of the above products. Please note that the packaging identified above for sterile products is not gas permeable.



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