STERILE SUPPLY

- Sharps Safety Station

Product Function

The Sharps Safety Station is used for organizing, counting & disposing of sharps.

Product Description

The disposable Sharps Safety Station is a single use product, and is supplied sterile.

The unique, patented Purple Surgical Sharps Safety Station™ range provides the ultimate in sterile sharps organisation, counting and disposal of contaminated sutures, blades and needles. This extensive range incorporates a number of unique safety features, which significantly reduce the risk of inadvertent sharps injuries.

- Patented, quick, simple and safe universal blade remover
- Unique, convenient integral scalpel shield for safe and simple scalpel storage and retrieval
- Unique locking mechanism prevents inadvertent opening whilst enabling re-counts if required
- Unique, secure, three hinge design prevents box opening during transportation
- Deep overlapping edges prevent accidental sharps migration
- Two size options to match surgical requirements
- Wide choice of formats, including foam blocks, magnetic surfaces, adhesive surfaces and foam strips, to match preference and clinical indication
- International bio-hazardous waste colour identification
- Colour:..... Yellow
- Dimensions..... 93 mm (Width) × 120 mm (Length) × 38 mm (Height)

Product Range

PS2940	Sharps Safety Station – Magnet and Foam Block, Large

Standardisation

Device Classification (Defined by 93/42/EEC Directive)	N/A – Non Medical Device
CE Marking	N/A
GMDN	N/A
Quality System Certified to	ISO 13485:2016

Sterilisation

Supplied in Sterile Condition	YES
Sterilisation Method	Ethylene Oxide
Product Shelf Life	5 years from date of sterilization

Single Use Warning

These device(s) are designed and sold for single use only as defined in Article 1 (n) of directive 2007/47/EC. As such re-processing and/or re-sterilisation after initial use is not permitted.

The effects of any unauthorized re-processing or re-sterilisation can result in the following complications:

1. Cross contamination due to ineffective re-processing/re-sterilisation.
2. Mechanical fatigue, and associated failure, due to the effects of the re-processing/re-sterilisation method.

Compatibility and Connectivity

Universal Blade Remover allows safe removal of scalpel blade.

Product Materials

Components	Material	Grade	CAS#
Box Shell	HIPS	825/Yellow Powder 1015040	N/A
Magnet	Magnet	EP7S	N/A
Magnet Adhesive	Siliconised Rubber Adhesive	DS10B	N/A
Securing Tab	PE foam double sided tape	F6B33	N/A
Release Liner	Polyethylene film liner coated with Silicone	N/A	N/A
Foam Block	PE/Adhesive	PA-60/FT9220	N/A
Foam Pull Tab	Siliconised Glassine Paper	N/A	N/A

Materials Data

The substances, which are contained in the Device, and require registration under REACH, have been (pre-) registered by our upstream suppliers. Substances, listed in Annex XVII of the EU Regulation No 1907/2006, concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), are not intentionally used or added in the formulation of the Device. However, since the product has not been tested for these substances, we cannot guarantee that there is no trace amount present, as impurity or otherwise.
The Device does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (SVHC) in a concentration above the threshold limit of 0.1 % (w/w) as stated in the REACH (Article 57).
The Device does not contain any of the biocides as stated in the EU Regulation No 528/2012 concerning biocidal products.

Latex Free	YES
Phthalate (DEHP, BBP & DBP) Free	YES

Packaging

Packaging	Blister Pouch (APET Clear Blister with TYVEK Medical Paper Lid)				
	Shelf Box		Shipping Carton		
Product Code	**Qty. (Pcs)**	**Dimensions (mm) (L × W × H)**	**Qty. (Pcs)**	**Dimensions (mm) (L × W × H)**	**Gross Wt. (Kg)**
PS2940	N/A	N/A	25	448 × 325 × 166	2.30Kg

Disposal

After single patient use, the device is to be immediately disposed of as controlled medical waste.

Availability of Instructions for Use:

YES ..... ☐

NO..... ☒

Storage and Handling Instructions:
Store and Handle with Care

Document Revision History

Revision	Change Detail	Date	Approved
1.	First Revision	Jun 2011	JH
2.	Shelf life updated from 4 – 5 years	Aug 2011	JH
3.	Securing tab material update	Aug 2011	JH
4.	Update of release liner material	Apr 2013	JH
5.	Inclusion of document change table	Feb 2014	KR
6.	Quality System Ref up date to reflect ISO13485:2016 & remove reference to ISO9001:2008	2018-10	CW
7.	Adding (L × W × H) in the Dimensions heading in the Packaging section and updating the Shipping Carton dimensions from 490 × 300 × 210 to 448 × 325 × 166. Insertion of REACH compliance statement into the Materials Data section.	2020-12	M. Cihal