Instructions for Use - iM CleanEST™ Pack

Intended Purpose
iM CleanEST™ is a simple, effective and safe system to ensure reprocessed endoscopes and equipment can be easily and hygienically stored and transported.

Description & Intended Use
The iM CleanEST™ pack contains a liner and two covers. It is intended to provide a clean tray liner with a cover to contain and protect a clean and disinfected endoscope during temporary storage and transportation to a procedure room or theatre. It is a single-use device.

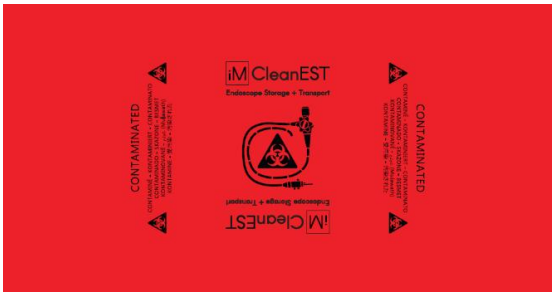
The device is specifically for use by trained healthcare decontamination staff.

The clean sterile liner is removed from the pack and placed within a transport tray. The disinfected flexible endoscope is placed on top of the liner and the green cover marked 'Clean' is stretched over the tray. The covers are coloured to indicate clean and dirty (green and red respectively).

Packs are irradiated using a 25 kGy dose. The irradiation process has been validated and audited in line with BS EN ISO 11137. The product is tested in accordance with BS EN ISO 11737 for sterility. Designed to fit the most common transport and storage trays currently in use.

Clear Identification
The iM CleanEST™ pack contains a single clear tray liner and two colour-coded tray covers, so decontaminated and contaminated endoscopes and equipment can be quickly and clearly identified:

- Green tray cover for "Clean", decontaminated endoscopes and equipment ready to use.
- Red tray cover for "Contaminated" endoscopes and equipment to be cleaned.



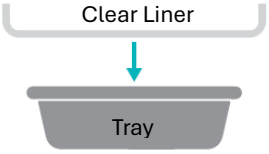
Close-up of Cover text

Contraindications
Do not use if the pack is damaged or the seal is not intact as the sterility of the pack will be compromised. The liner and covers contained within the pack should be considered contaminated and should not be used. The contents of the pack are for single-use and not for reuse. Reprocessing or re-sterilisation is not permitted.

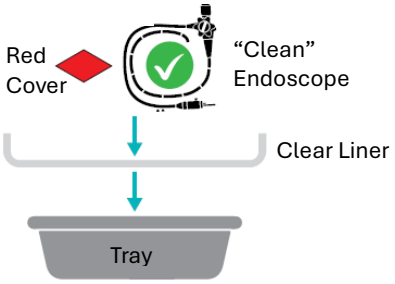
Precautions & Residual Risks
The product has been designed to minimise risks, but users should ensure tray liners and covers are positioned correctly to avoid accidental contamination. Check for visible damage (tears or incomplete coverage) prior to use. If the tray liner or cover becomes torn during use discard the affected component and replace it with a new pack. Incorrect colour coding may lead to use error. Ensure the green cover is applied for clean devices and the red cover for contaminated devices; if applied incorrectly, reapply the appropriate cover before transport to avoid confusion.

Instructions for Use

1. Line the tray with the clear liner.



2. Place the decontaminated endoscope and the folded red tray cover into the tray.

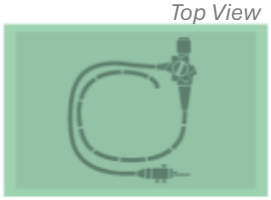


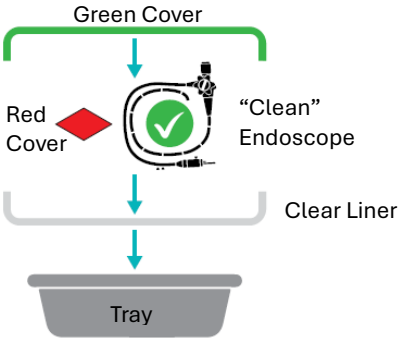
3. Cover with the green tray cover.

"Clean" Endoscope within lined tray with green cover

Side View

Top View





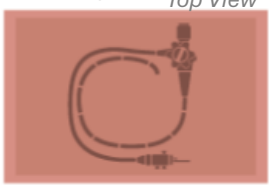
4. Remove the green tray cover when ready to use the endoscope, leaving the clear liner and folded red tray cover in the tray. As the green cover does not come into contact with contamination, it may be recycled if permitted by local policy.

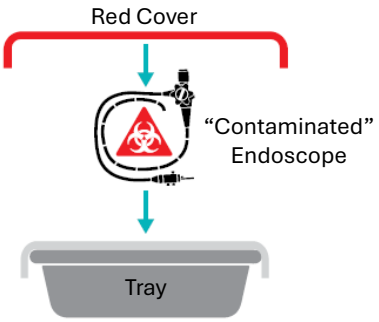
5. When finished, take out the folded red tray cover, place the contaminated endoscope back into the tray (on the existing clear liner), then place the red tray cover over the tray.

"Contaminated" Endoscope within lined tray with red cover

Side View

Top View





6. Once the liner and cover have been used to return the medical device for reprocessing, they should be treated as being contaminated and dispose of accordingly i.e. treated in line with hospital policy for disposal.

Disposal Methods

After use, the liner and red cover should be treated as contaminated and disposed of in accordance with local or hospital policy for contaminated waste. As it has not been in contact with contamination, the green cover may be recycled if permitted by local policy.

Technical Details

Raw Materials	Liner & Covers Materials	
	High molecular weight High Density Polyethylene (HDPE)	
	Low Density Polyethylene (LDPE)	
	Butene Linear Low Density Polyethylene (LLDPE) TNPP free	
	Outer Pack Materials	
	PET+PE composite film	
This product and its packaging contain no natural rubber latex.		
Film Properties	Tested in accordance with:	
Polymer properties	HDPE - ISO 1133 & ASTM D1505; LDPE & LLDPE - ASTM 1238 & ASTM D1505	
Mechanical Properties	ASTM D1709	
Tensile Strength (HDPE)	ASTM D1922	
Tensile Properties	ASTM D882, ASTM D1922	
Thermal Properties	ASTM D1525	
Optical Properties (LDPE & LLDPE)	ASTM D1003 & ASTM D2457	
Dimensions		
Tray Liner	880 x 385mm (LxW)	
Red & Green Cover	730 x 390mm (LxW)	
Pack	145 x 130mm (LxW)	
Shelf Life	Storage Conditions	
iM CleanEST™ has a two-year shelf life.	Store in a dry and cool area. Keep away from heat sources and sources of ignition. Keep away from direct sunlight.	
Classification		
iM CleanEST™ has been classified as a Class I Sterile (Is) Medical Device, under the criteria in both the UK MDR 2002 (as detailed in Annex IX of the Medical Device Directive 93/42, under Rule 1) and the EU Medical Device Regulation (EU MDR 2017/745, Annex VIII, under Rule 1). The product is both UKCA and CE marked.		
UDI-DI	05060603030694	

Order Details

Catalogue Number	Description
125010	iM CleanEST™ Endoscope Storage and Transportation System, Box of 200

Information on the Product: Symbols shown on the product label			
Symbol	**Description**	**Symbol**	**Description**
	Catalogue number		Indicates the product is a medical device
	Indicates the product manufacturer		Indicates the product is for single-use
	Indicates the date of manufacture Date format: YYYY/MM		Indicates the EU authorised representative
	Expiry date Date format: YYYY/MM		Batch or Lot Number
	Sterilised using irradiation		Do not use if package is damaged and consult instructions for use
	Product contains no latex		

Notice Regarding Serious Incidents

Please note that any serious incident that has occurred in relation to our iM CleanEST™ product should be reported to iM Med and the competent authority of the Member State in which the user and/or patient is established. Contact details are shown at the end of these instructions for use.

If you are in the UK the competent authority is the Medicines and Healthcare products Regulatory Agency (MHRA). Details on how to report this are provided on the MHRA website as follows:
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Within the NHS there are reporting systems established for advising the regulator so this method can also be followed.

For Europe

To find the details of your competent authority please go to:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

iM Med has an appointed EU authorised representative please see their details below.

Supplied & Manufactured by:

iM Med Limited, 1 Pembroke Avenue, Waterbeach, Cambridge, CB25 9QP, UK

Tel: +44 (0)1223 440475 Email: enquiries@im-med.com

EU REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta