DISPOLINE® HEALTHCARE

BECAUSE... YOU MATTER

INPREV™ INFECTION PREVENTION

SOLUTIONS & EXPERIENCES IN INFECTION PREVENTION

- ☑ **MANUFACTURING UNDER CLEAN ROOM CONDITIONS** as per ISO 14644
- ☑ **VALIDATED STERLIZATION PROCESS & SEALING PROCESS** as per ISO 11135 & ISO 11607
- ☑ **CERTIFIED QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES** as per ISO 13485 : 2016 by TUV Rheinland

TÜVRheinland® CERTIFIED
www.tuv.com

- EN ISO 13485: 2016 + AC:2016 QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

SINGLE USE

CUSTOM - ENGINEERED SURGERY SPECIFIC STERILE PROCEDURE KITS

www.dispoline.in

Partial Product List

SINGLE USE
CUSTOM - ENGINEERED SURGERY SPECIFIC
STERILE PROCEDURE KITS

CARDIOLOGY
- CABG KIT
- ANGIOGRAM KIT
- ANGIOPLASTY / PTCA KIT
- ADULT DRAPE KIT
- PAEDRIATRIC DRAPE KIT
- INFANT DRAPE KIT
- VALVE REPLACEMENT KIT

TRANSPLANT SURGERY
- KIDNEY TRANSPLANT KIT
- LIVER TRANSPLANT KIT

GENERAL SURGERY
- GENERAL PACK
- GENERAL DRAPE KIT
- LAPROSCOPY PACK
- PERINEAL PACK
- LAPAROTOMY PACK
- GENERAL PACK - PLASTIC SURGERY

GYNAECOLOGY
- NORMAL DELIVERY KIT
- D & C KIT
- CAESERIAN KIT
- HYSTERECTOMY PACK
- LSCS PACK

UROLOGY / NEPHROLOGY
- TURP PACK
- CYSTOSCOPY PACK
- UROLOGY PACK
- A V FISTULA KIT

ORTHOPAEDICS
- ORTHO. PACK
- THR PACK
- TKR PACK
- SPINAL SURGERY PACK
- MINI ORTHO. PACK
- ARTHROSCOPY PACK
- LEG U DRAPE
- ARM U DRAPE

NEUROSURGERY
- HEAD PACK
- CRANIOTOMY PACK
- LAMINECTOMY PACK
- BURR HOLE PACK
- NEURO SPINE PACK

OPTHALMOLOGY
- CATARACT PACK
- LASIK PACK
- EYE PACK
- EYE DRESSING KIT

ENT
- ENT PACK

CRITICAL CARE
- ICU UTILITY KIT
- CENTRAL LINE KIT
- DRESSING KIT
- CATHETERIZATION KIT
- MINOR PROCEDURE SHEET

INDIVIDUAL PATIENT DRAPES

INSTRUMENT COVERS & OT TABLE COVERS

SURGEON GOWN
- SMMMS/SSMMS
  Standard / Reinforced /
  Alcohol Repellent & Anti.Static
- VIRAL BARRIER GOWNS

GOWNS
- ISOLATION GOWN
- PROCEDURE GOWN
- PATIENT GOWN
- FEEDING GOWN

STERILE BARRIER SYSTEMS

CERTIFIED WRAPS AND STERILE FIELDS
- SMMMS / SSMMS

OT ATTIRE

- **MASKS**
- 3 PLY WITH BACTERIAL FILTER
  (TIE / ELASTIC)
- 4 PLY WITH ANTI FOG VISOR
- 4 PLY WITH ACTIVATED CARBON
- N95

- **CAPS**
  BOUFFANT CAP
  SURGEONS HOOD
  SURGEON CAP

- **SHOE COVER**
- **PROTECTIVE EYEWEAR**
- **O.T APRON**
- **DRAWSHEET**
- **OT WIPES**

PATIENT CARE

- CRITICAL CARE VISITOR PACK
- ADMISSION KIT
- ATTENDERS GOWN KIT
- WIPES
- MITTS
- BED SHEETS
- EXAMINATION TABLE SHEET
- PILLOW COVER
- OPD SHEETS
- LADIES HOSPITAL BRIEF
- UNDERPAD
- ADULT DIAPERS

DISPOLINE® HEALTHCARE

BECAUSE... YOU MATTER

INPREV™ INFECTION PREVENTION

SOLUTIONS & EXPERIENCES IN INFECTION PREVENTION

TÜVRheinland® CERTIFIED

www.tuv.com

- **EN ISO 13485: 2016 + AC:2016**
- **QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES**

The products are manufactured at modern manufacturing facilities having Controlled Enviromental Conditions & Process Specific Cleanrooms

1. The Sterilization process has been validated according to ISO 11135 standards and a protocol is established to ensure the process repeatedly delivers Sterility Assurance Level 10-6 (SAL) to the product.
   A set of 16 Biological indicators (1.5 BI's per Cu. Mtr) are sent with each batch of sterilization for routine monitoring of the sterilization process, and then incubated for 48 hours @37 degrees before the product is released. All packs have Internal and External chemical indicators for a visual check of exposure to ETO.
   The internal chemical indicators are peel off labels with batch & production details, printed on them, in order to transfer them to patient records for traceability.

2. Pouch Packaging conforms to EN 868 and are sourced from a manufacturer who conforms to EN ISO 13485 & ISO 11607 - 1

3. Packaging Sealing is done by state of the art machines with online printing and the sealing process is validated as per EN ISO 11607-2, and have an integrated system to evaluate critical parameters like Pressure, Temperature and Time and these are recorded. To ensure traceability protocols are met.

4. The medical fabrics are sourced from the best manufacturers around the globe and conform to various standards as per product applications as well as specific customer requirements.
   Some of the standards applied are AAMI PB70, EN 13795, EN ISO 11607 etc.

5. Our Medical Fabrics undergo Batch/Run Wise Monitoring of Critical Quality Parameters and are documented.

6. The medical fabrics are also subjected to Cytotoxicity and Skin (Dermal Irritation) Tests.

7. Residual tests for Ethylene Oxide, Ethylene Chlorohydrin & Ethylene Glycol as per ISO 10993-7

8. Sterility Tests done as per ISO 11737-2

9. Bioburden Analysis done as per ISO 11737-1

10. Usage based sealing methods are followed
    - Ultrasonic Sealing • Impulse heat Sealing • Hot Melt Glue • Adhesive Tapes • Conventional Stitching.

11. All traceability protocols with regard to the product and raw materials are followed.

www.dispoline.in

DISPOLINE® HEALTHCARE

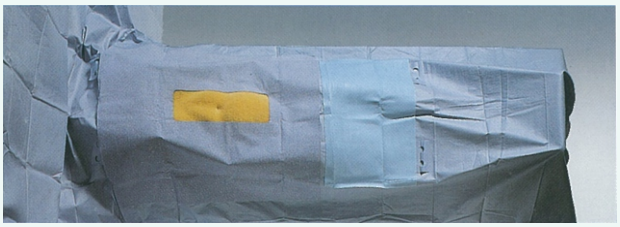
BECAUSE... YOU MATTER

INPREV™ INFECTION PREVENTION

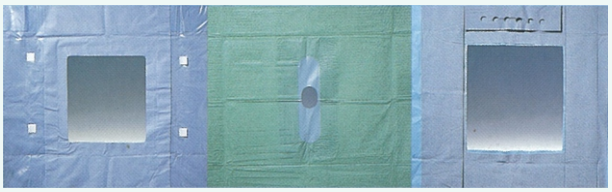
SOLUTIONS & EXPERIENCES IN INFECTION PREVENTION

SINGLE USE CUSTOM - ENGINEERED SURGERY SPECIFIC STERILE PROCEDURE KITS

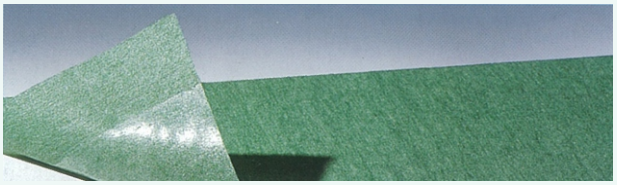
REDUCED COST, INFECTION PREVENTION, TIME SAVING



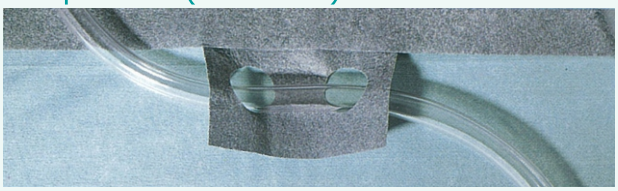
- microbiological barrier
- procedure specific designs



- usage based sealing methods
- conformable fenestrations
- impervious (reinforced)

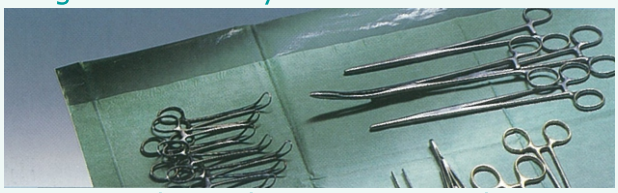


- adhesive edges and tapes
- ease of use



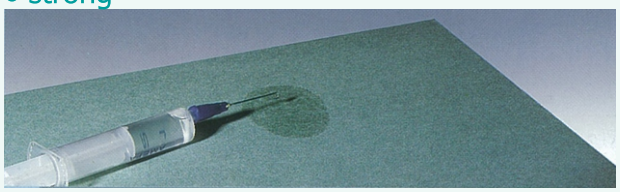
- tube holders
- greater flexibility

- fluid collection pouches
- always clean



- integrated non-slip instrument pads
- strong

- breathable where needed
- comfort



- fluid absorbency where required
- soft & drapeable

- less storage place
- ease of disposal
- minimisation of waste

- simplification of inventory
- effective consumption controls

- sterile
- validated sterilization process
- pouch packaging conforms to international standards
- validated sealing process
- all traceability protocols followed
- faster reaction time in emergencies

- lower capital binding
- global standards
- medical fabrics sourced from global leaders & batch wise monitoring of critical parameters
- regular bio-burden analysis, sterility test as well as eto residual tests
- cytotoxicity & dermal irritation testing

DISPOLINE INDIA PRIVATE LIMITED

H.O. & Works : # 62,63,68,69, 1st Cross, Muniswamappa Layout, Off Hosur Road, Bommanahalli, Bangalore - 560 068

✆ : +91-80-4120 2090 / 91 +91-8088031446 **info@dispoline.in, bangalore@dispoline.in**

CHENNAI	HYDERABAD	KOLKATA	MUMBAI & PUNE	DELHI	KERALA
+91-9003041335	+91-40-2790 1460	+91-33-2335 4845	+91-80-41202090	+91-9818664063	+91-80-41202090
chennai@dispoline.in	hyderabad@dispoline.in	kolkata@dispoline.in	info@dispoline.in	delhi@dispoline.in	info@dispoline.in

www.dispoline.in