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# STERILIZING PACKAGING SOLUTIONS

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# INDEX

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About us	01
Introduction	02
Quality Control System	03
Sterile Barrier System	04
01. Heat-Sealing Sterilization Reels and Pouches Flat	05
02. Self-Seal Sterilization Pouches – Paper/Film	08
03. Sterilization Reels and Pouches Flat- Tyvek/Film	10
04. Wrapping Material Crepe Paper	12
05. Wrapping Material Non-woven – SMS/ SMMS/ SMMMS Fabric	14
Chemical Indicator Tapes	16
Chemical Indicator Strips	18
Bowie Dick Test Pack/Paper	21
Notes	23

# KONKORE PACKAGING PRIVATE LIMITED

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## About us

Konkore Packaging Private Limited was incorporated on 9th June, 2017. The company specializes in the manufacturing of sterilization reels and pouches.

The company is equipped with highly efficient automated machinery for the production of sterilization reels and pouches. The safety standards required during the production are strictly followed with regards to high product quality and maximum efficiency.

The management is diversified with experience in different areas of manufacturing which is an important aspect for a stable and well-organized structure.

The company has a process chart that divides the work flow towards the road to maximum quality production. Moreover, the company carries valuable reputation among its clients.



## Corporate Philosophy

Customer Management is one of the key aspects of the company which constantly deals in increasing the work efficiency and understanding the customers' requirements.

The company is committed in fighting against infections by manufacturing sterilized packaging products and by supplying them to medical device manufacturers, hospitals, pharmaceutical companies etc.

# INTRODUCTION

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## 01. What is the sterilization packing for medical instrument?

Defined as EN-868 & ISO-11607, it is the primary packaging for medical instruments with microorganism Barrier, Sterilizable, and sustained and Shelf-life performances.

## 02. How to design for sterilization packing of disposable medical instruments?

When choosing sterilization packing for medical instruments, you should consider the following factors:

- a. Methods of sterilization
- b. Volume and weight of the loading instrument
- c. Validated date
- d. Convenience of use



# QUALITY CONTROL SYSTEM

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Konkore complies with internationally recognized quality, and maintains a strict quality control system for controlling all aspects of the manufacturing process. Beginning from sourcing raw materials, testing, packing, inventory and deliveries.

## Quality Certifications and Registrations

Konkore acts in accordance with Global Standards for the medical packaging products ISO 14971, ISO 11607, ISO 13485.

## Quality Assurance Section

### 01. Raw material Sourcing

High quality and efficient suppliers, strict process of incoming inspection by IQC.

### 02. Production

Class 100,000 grade clean workshop. The production process is continuous with a customized process chart made by the company.

### 03. Testing

First Article Inspection: The product consistency is ensured and sample drafts are manufactured and tests as per standards and requirements.

### 04. Quality Inspection

The quality of the product is checked and analyzed during the various stages of the manufacturing of the final product by The QC department. This helps in maintaining the quality of the finished product.

### 05. Storage and Packing

The segregation of unqualified goods are done at the beginning and are separated and then discarded. The final finished goods are safely packed as per the packing standards.



# STERILE BARRIER SYSTEM

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The term “sterile barrier system” refers to the minimum packaging that prevents proliferation of microorganisms and sterilizing the product to prepare it when it’s time for use. This is where medical pouch sealers play an important role in ensuring that a medical device is safe and sterilized while it’s not being used.

No matter how strict your process of sterilization and disinfection is, you can still have the risk of contaminating your product. This can happen when your packaging and seal closure system is compromised during shipment and storage and could cause serious danger to the user.

The product may be considered a complete sterile barrier system only when it has passed a complete testing protocol and the manufacturer has applied the final seal. This is the only time that the entire packaging system can be considered compliant as per ISO 11607.



## 01. Heat-Sealing Sterilization Reels and Pouches

### Flat and Gusseted – Paper/Film

Konkore heat-sealing sterilization reels and pouches are universal packing solution for sterilization applications. They ensure reliable and effective protection of the medical equipment against contamination with bacteria from the time of sterilization until the use of the sterile medical equipment.

The Flat and Gusseted type of reels have a wide range of standard sizes which is generally suitable for all the packaging demands of light and medium weight medical devices and instruments.

Konkore heat-sealing sterilization reels and pouches are manufactured from medical grade paper and transparent CPP/PET multi-layer copolymer film. There are two water based non-toxic process indicators for steam and ethylene oxide sterilization which are imprinted on the paper surface which prevents the instrument from getting coloured and helps to differentiate between processed and unprocessed packaging. Formaldehyde indicator is also available if requested.



## Brief advantages of Konkore Heat-Sealing Sterilization Reels and Pouches

1. Medical grade paper with technic 60gsm or 70gsm is an effective barrier against germs and bacteria. Despite of this, it permits the transmission of air, steam or sterilization gas.
2. It has a reinforced film to avoid tear during opening.
3. The Peel-Easy film permits film separation from paper without any shattering.
4. It has a clean and accurate indicator colour change.
5. It has tear, fiber-free opening and aseptic presentation.
6. It has a triple band seal for higher package integrity which effectively avoids cracking.

## Standards

Konkore heat-sealing sterilization reels and pouches comply with EN868 and ISO11140-1 standards.

### Specification Sheet

Konkore heat-seal sterilization reels flat-paper/film

Catalogue No.	Sizes	Pack(Reels/CTN)
KONFR-050200	50 MM(2") X 200 METERS	12
KONFR-055200	55 MM(2.2") X 200 METERS	12
KONFR-075200	75MM(3") X 200 METERS	8
KONFR-100200	100 MM(4") X 200 METERS	6
KONFR-150200	150 MM(6") X 200 METERS	4
KONFR-200200	200MM(8") X 200 METERS	2
KONFR-250200	250MM(10") X 200 METERS	2
KONFR-300200	300MM(12") X 200 METERS	2
KONFR-350200	350 MM(14") X 200 METERS	2
KONFR-400200	400MM(16") X 200 METERS	2
KONFR-450200	450 MM(18") X 200 METERS	2
KONFR-500200	500MM(20") X 200 METERS	2
KONFR-600200	600MM(24") X 200 METERS	2



## Gusseted Reels- Paper/ Film

Konkore heat-seal sterilization reels gusseted paper/film

Catalogue No.	Sizes	Pack(Reels/CTN)
KONGR-075200	75 MM(4") X 100 METERS	8
KONGR-100200	100 MM(2") X 100 METERS	6
KONGR-150200	150 MM(2") X 100 METERS	4
KONGR-200200	200 MM(2") X 100 METERS	2
KONGR-250200	250 MM(2") X 100 METERS	2
KONGR-300200	300 MM(2") X 100 METERS	2
KONGR-350200	350 MM(2") X 100 METERS	2
KONGR-400200	400 MM(2") X 100 METERS	2

## 02. Self-Seal Sterilization Pouches- Paper/Film

Konkore self-seal sterilization pouches are pre-folded and they assure quick and secure closing without a heat sealer. They are especially suited for use in small general practice, dental surgeries and by users who do not want to pay additional costs of sealing devices.

Konkore self-seal sterilization pouches are constructed from medical grade paper and transparent CPP/PET multi-layer copolymer film and adhesive strip. The two water based, non-toxic process indicators for steam and ethylene oxide sterilization are imprinted on the paper surface which prevents the instrument from getting coloured and helps to differentiate between processed and unprocessed packages.



### Brief Advantages of Konkore Self-Seal Sterilization Pouches

1. Medical grade paper with technic 60gsm or 70gsm is an effective barrier against germs and bacteria despite of that it permits the transmission of air, steam or sterilization gas.
2. It has a reinforced film to avoid tear during opening.
3. The Peel-Easy film permits the film separation from paper with no shatters.
4. It has a clean and accurate indicator colour change.
5. It has tear, fiber-free opening and aseptic presentation.
6. It has a triple band seal for higher package integrity which effectively avoids cracking.

## Standards

Konkore self-seal sterilization pouches comply with EN868, ISO11607 and ISO11140-1.

### Specification Sheet

Konkore Self-Seal Sterilization Pouches

Catalogue No.	Sizes	Pack(Pieces/Box)
KONSSP-057130	57MM X (100+30)MM	200
KONSSP-070260	70MM X (230+30)MM	200
KONSSP-090165	90MM X (135+30)MM	200
KONSSP-090260	90MM X (230+30)MM	200
KONSSP-135280	135MM X (250+30)MM	200
KONSSP-190360	190MM X (330+30)MM	200
KONSSP-200320	200MM X (290+30)MM	200
KONSSP-200360	200MM X (330+30)MM	200
KONSSP-230395	230MM X (365+30)MM	200
KONSSP-305430	305MM X (400+30)MM	200
KONSSP-400535	400MM X (505+30)MM	200
KONSSP-500630	500MM X (600+30)MM	200

### 03. Sterilization Reels and Pouches Flat – Tyvek/Film

#### TYVEK is the Trade Mark of DUPONT.

Tyvek is a non-woven polyethylene fabric manufactured by Dupont®. It is known for its outstanding strength, durability and tear resistance. It is used for Industries related to EO and Gamma sterilization. Tyvek is not suitable for steam sterilization, however it is perfectly compatible with the requirements of Vh202 (plasma) sterilization. It is also used as a primary option for gas sterilization as Tyvek hardly absorbs any toxic gases and thus results in for below legal limit values of residual toxic gas levels.

Konkore Tyvek sterilization reels and pouches are made of uncoated Tyvek and transparent multi-layer PET/PP copolymer film is decisively determined by the choice of the material. The two water based, non-toxic process indicators for hydrogen peroxide sterilization are imprinted on the Tyvek surface which prevents the instrument from getting coloured and helps to differentiate between processed and unprocessed packages. The Formaldehyde indicators are also available, if requested.



## Brief Advantages of KonkoreTyvek Sterilization Reels and Pouches

1. They have excellent microbial barrier properties against germs, bacteria and moisture.
2. They have very high resistance to penetration and has fiber-free peeling.
3. They can be easily peeled and has aseptic presentation.
4. They have clear and accurate colour change.

## Standards

Konkore Tyvek Sterilization reels and pouches comply to En868, ISO11607 & ISO11140 standards.

### Specification Sheet

Konkore Sterilization reels flat- Tyvek/film

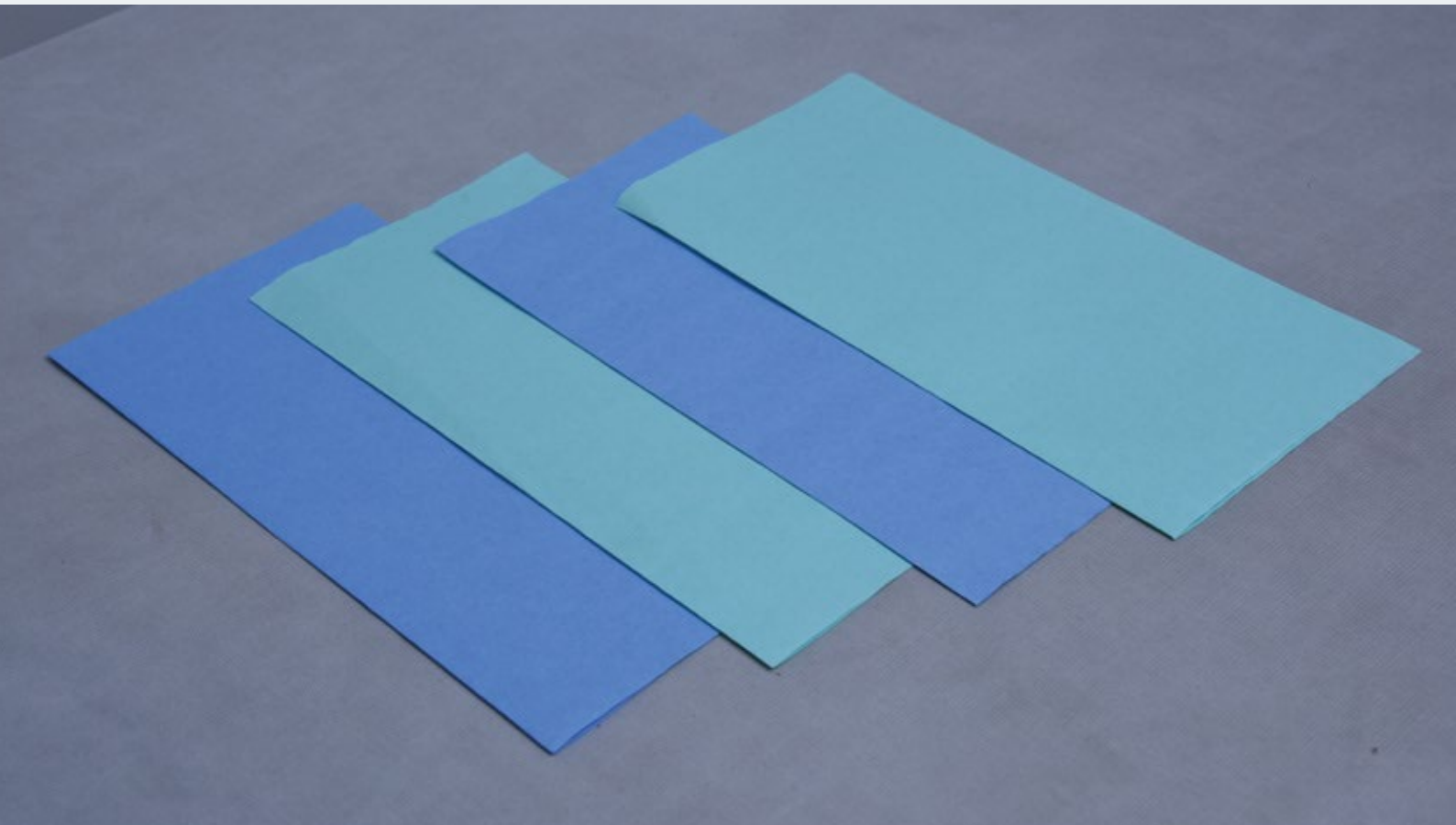
Catalogue No.	Sizes	Pack(Pieces/Box)
KONTR-050100	50MM (2") X 100METER	12
KONTR-055100	55MM (2.2") X 100METER	12
KONTR-075100	75MM (2") X 100METER	8
KONTR-100100	100MM (2") X 100METER	6
KONTR-150100	150MM (2") X 100METER	4
KONTR-200100	200MM (2") X 100METER	2
KONTR-250100	250MM (2") X 100METER	2
KONTR-300100	300MM (2") X 100METER	2
KONTR-350100	350MM (2") X 100METER	2
KONTR-400100	400MM (2") X 100METER	2
KONTR-500100	450MM (2") X 100METER	2



## 04. Wrapping Material Crepe Paper

Konkore crepe wrapping paper is made up of 100% medical quality cellulose fibers and it combines with the most economic wrapping with good drop-ability property i.e. water resistant. It is a suitable and particular packaging solution for lighter instruments and sets. Also, it can be used for inner and outer wrapping.

Crepe is suitable for Steam sterilization, Ethylene Oxide sterilization, Gamma Ray sterilization and Irradiation sterilization or Formaldehyde sterilization in low temperature and is a reliable solution for preventing cross contamination with bacteria. The colour of crepe offered by Konkore is green along with standard sizes. Moreover, customization of sizes is available, as per request.



### Brief Advantages of Konkore Crepe Wrapping Paper

1. It is available in 60gsm.
2. Medical grade paper with no smell, no powder and non-toxic.
3. It has excellent water resistance and bursting strength.

4. It has high bacterial filtration efficiency (BFE).
5. It is a proven microbial barrier.

## Specification Sheet

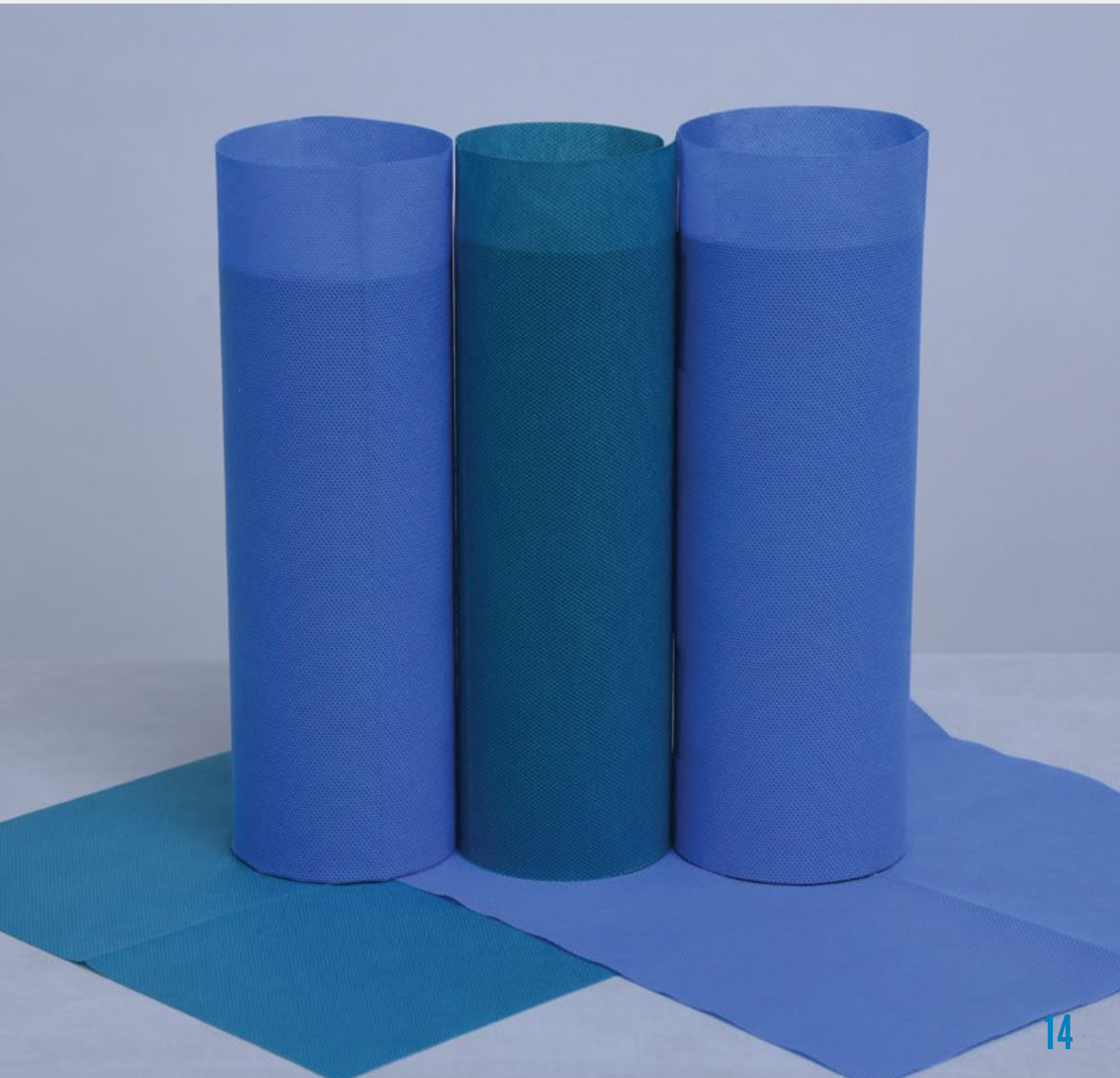
Konkore wrapping material crepe paper

Catalogue No.	Sizes	Pack(Pieces/Box)
KONCR-3030	30 CM X 30 CM (11")	2000
KONCR-4040	40 CM X 40 CM (16")	1000
KONCR-4545	45 CM X 45 CM (18")	1000
KONCR-5050	50 CM X 50 CM (20")	1000
KONCR-6060	60 CM X 60 CM (24")	1000
KONCR-7575	75 CM X 75 CM (30")	500
KONCR-9090	90 CM X 90 CM (35")	250
KONCR-100100	100 CM X 100 CM (40")	250
KONCR-120120	120 CM X 120 CM (47")	200
KONCR-150150	150 CM X 150 CM (60")	200

## 05. Wrapping Material Non-woven – SMS/SMMS/SMMMS Fabric

Konkore SMS, SMMS and SMMMS non-woven fabric are considerably water-proof and resilient. The non-woven material is made up of polypropylene fabric layers. They can be used either as inner or outer wrapping for medical devices. They are available in 43g for regular weight, 50g for heavy duty and 60g for multi-pack.

SMS, SMMS and SMMMS wraps that are single or double wrapped are suitable for steam, ethylene oxide, hydrogen peroxide, plasma and irradiation sterilization methods. The memory free feature before and after sterilization ensures good aseptic presentation.



## Comparison of SMS, SMMS and SMMMS non-woven Fabric with 43g, 50g and 60g

Type	Layers	Construction	Features	Weight	Features
SMS non-woven fabric	three	Two layer spunboard; one layer meltblown non-woven inside	Waterproof; Breathable, Antibacterial, Low shrinkage rate	SMS/SMMS/ SMMMS 43g	Light duty applications
SMMS non-woven fabric	Four	Two layer spunboard; one layer meltblown non-woven inside	Waterproof; good Air Permeability, Better Anti Bacteria, Resistance to tears and punctures	SMS/SMMS/ SMMMS 43g	All kinds of wrapping applications
SMMMS non-woven fabric	Five	Two layer spunboard; one layer meltblown non-woven inside	Waterproof; Higher barrier protection and high level of Air Permeability Strong resistance to tears and punctures	SMS/SMMS/ SMMMS 43g	Heavy Duty Applications

## Specification Sheet

Konkore wrapping material non-woven

Catalogue No.	Sizes	Pack(Pieces/Box)
KONNW-3030	30 CM X 30 CM (11")	2000
KONNW-4040	40 CM X 40 CM (16")	1000
KONNW-4545	45 CM X 45 CM (18")	1000
KONNW-5050	50 CM X 50 CM (20")	1000
KONNW-6060	60 CM X 60 CM (24")	500
KONNW-7575	75 CM X 75 CM (30")	250
KONNW-9090	90 CM X 90 CM (35")	250
KONNW-100100	100 CM X 100 CM (40")	200
KONNW-120120	120 CM X 120 CM (47")	200
KONNW-150150	150 CM X 150 CM (60")	200

# CHEMICAL INDICATOR TAPES

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Konkore chemical indicator tapes are ideal and provide safe solutions for closing all wrapping materials. They are manufactured by generating pressure from semi-crepe paper whose one side has the adhesive glue and the other side has the indicator strip. The process indicator ink shows an easy and accurate colour change and indicates if the pack has been processed.

The Konkore chemical indicator tapes are designed from steam, E.O. Gas, Plasma and Formaldehyde sterilization processes and also provide a clean peel from the wrapping material. All chemical indicator tapes are available on the OEM and ODM.

## Features

1. Konkore Process indicator tapes are used as external exposure control indicators for steam, plasma and EO gas sterilization.
2. Konkore Process indicator tapes can be used to seal packages that are to be sterilized.
3. Konkore indicator tapes are self-adhering on one side and chemical indicator (Class 1) on the other side.
4. It shows distinct colour change from light to dark.
5. The utility of Konkore process indicator tapes is to distinguish between processed and unprocessed articles and to indicate whether the particular pack exposed to sterilization process or not.
6. Konkore process indicator tapes are made of lead-free, non-toxic ink. Due to strong but latex free adhesive Konkore process indicator tapes do not leave any residue on the non-woven or woven surface.
7. Konkore plasma, steam and EO gas indicator tapes are available in rolls of 55 Meters in length.
8. Konkore masking tapes are also available to seal the packages.

## Standards

Konkore chemical indicator tape comply to En867 and ISO11140 standards.





## Specification Sheet

Konkore Chemical Indicator Tapes

Description	Catalogue No.	Size	Pack (Pieces/CTN)	Colour Change
Steam Indicator Tapes	KONSIT-1250	12MM X 50MTR	76 ROLLS/CTN	Turn to Black (processed) from Beige (unprocessed) under steam sterilization.
	KONSIT-1950	19MM X 50MTR	48 ROLLS/CTN	
	KONSIT-2550	25MM X 50MTR	36 ROLLS/CTN	
EO Indicator Tape	KONEIT-1250	12MM X 50MTR	76 ROLLS/CTN	Turn to Green (processed) from Red (unprocessed) under EO gas sterilization.
	KONEIT-1250	19MM X 50MTR	48 ROLLS/CTN	
	KONEIT-1250	25MM X 50MTR	36 ROLLS/CTN	
Plasma Indicator Tape	KONPIT-1250	12MM X 50MTR	76 ROLLS/CTN	Turn to Wine-Red (processed) from Blue (unprocessed) under plasma sterilization.
	KONPIT-1950	19MM X 50MTR	48 ROLLS/CTN	
	KONPIT-2550	25MM X 50MTR	36 ROLLS/CTN	

# CHEMICAL INDICATOR STRIPS

Konkore chemical indicator strips are manufactured in the absence of lead or other heavy metals. They are manufactured from a special card, standard colour patch and indicator strip. The process indicator ink shows clear and accurate colour change and indicates if the pack has been processed. The Konkore Chemical Indicator strips are designed for steam, E.O. gas and plasma sterilization process and are Sticker based/Laminated.



## Steam Indicator Strips Class 4

### Features

1. Class 4 steam chemical indicators are multivariable indicators that are designed to react to two or more of the critical variables and are intended to indicate exposure to a sterilization process at a stated value of the chosen variables.
2. These are placed inside each pack for the user to know the sterilization of the pack contents.
3. Class 4 indicators are primarily used in gravity displacement sterilizers as these machines cannot ensure the availability of all the sterilization parameters.
4. Class 4 indicators confirm to ISO11140-1.

Pack Size: 400 strips

## Steam Indicator Strips Class 5

### Features

1. Class 5 chemical indicators are integrating indicators that are designed to react to all critical variables. The Standard values are generated to be equivalent to or exceed the performance requirements given in the ISO 11138 series of Biological Indicators.
2. Class 5 indicator meets all the critical parameters required for effective sterilization.
3. Class 5 chemical indicators confirm to ISO11140-1.

Pack Size: 400 Strips

## Steam Indicator Strips Class 6

### Features

1. Class 6 Emulating indicators are cycle verification indicators which are designed to read to all critical variables for specified sterilization cycles. The standard values are generated from the critical variables of the specified sterilization process.
2. Konkore Emulating Indicators are specialized indicators that emulate the conditions of a specific cycle i.e. either 121°C or 134°C.

3. Konkore Class 6 Emulating indicators are basically cycle verification indicators and used in validating pre-vacuum cycles availability.

## ETO Indicator Strips Class 4

### Features

1. Class 5 chemical indicators are integrating indicators that are designed to react to all critical variables. The Standard values are generated to be equivalent to or exceed the performance requirements given in the ISO 11138 series of Biological Indicators.
2. Class 5 indicator meets all the critical parameters required for effective sterilization.
3. Class 5 chemical indicators confirm to ISO11140-1.

**Pack Size: 400 strips**

### Standards

Konkore Chemical Indicator strips comply with EN867 and ISO11140 standards.

Specification Sheet				
Konkore Chemical Indicator Strips				
Product	Catalogue No.	Sizes	Pack (Pieces/Box)	Colour Change
Steam Indicator Strip with Sticker	KONSIS-CLASS 4	15MM X 100MM(4")	400 PCS/BOX	Turn Black from Blue
	KONSIS-CLASS 5	20MM X 70MM(3")	400 PCS/BOX	Turn Dark Blue from Blue
	KONSIS-CLASS 6	20MM X 107MM(4")	400 PCS/BOX	Turn Black from Yellow
ETO Indicator Strip with Sticker	KONEIS-CLASS 4	15MM X 100MM(4")	400 PCS/BOX	Turn Blue from Red

# BOWIE DICK TEST PACK/PAPER

Konkore Bowie dick Pack/Paper are pre-assembled and single use test packs designed for the detection of defects in the sterilization process. An indicator sheet printed with water based, non-toxic chemical indicator. The colour changes from yellow to black from the indicator after steam sterilization indicates that all air was removed and replaced by steam.



## Brief Advantages of Konkore Bowie Dick Test Pack/Paper

1. They are easy to read test sheet with detailed instructions for use and interpretations of results.
2. They have small sizes for easy handling and storage.
3. They have external process indicator for ready identification of processed test packs.
4. They are totally reproducible and the test sheet will stay flat after the sterilization cycle.

## Standards

Konkore Bowie Dick Test Pack/Paper comply with ISO11140-1, EN867-4 and ISO11140-4.



## Specification Sheet

Konkore Bowie Dick Test Pack/Paper

Description	Catalogue No.	Size
Bowie Dick Test Pack/Paper	KONBD-01	115MM X 125MM
Bowie Dick Test Paper	KONBD-02	210MM X 300MM

## Features

1. “Konkore Bowie Dick” is a compact Bowie Dick Type test pack.
2. “Konkore Bowie Dick” is a daily steam penetration test for detecting air leakages and the presence of non-condensable gases in dynamic air removal steam sterilizers.

## Method

The test pack is placed in the sterilizer in the area which is the most difficult to sterilize and run through a sterilization cycle for 3.5 minutes at 134°C. An air removal failure/leakage is indicated as a lighter-coloured area in the centre of an otherwise dark-coloured test sheet.

## Quality

1. “Konkore Bowie Dick” is made from unbleached paper loads and lead-free indicator inks, eliminating the headaches of a safe disposal.
2. “Konkore Bowie Dick” Test Pack confirms to ISO1140-1, Class-2 Standards. The performance of “Konkore Bowie Dick” is equivalent to the Bowie-Dick towel Pack, as described in ANSI/AAMI ST79.
3. Bowie Dick Test Sheets of size 200MM X 250MM are also available.

## Additional features of “Konkore Bowie Dick” Test Pack

1. Unique Design
2. Meeting all standards
3. Unique and never before thumb cut for convenience of taking out the test sheet
4. Convenient pack, goes to sterilizer as it is.
5. Unique designs with highest catchments area for detecting non-condensable
6. gases.Sharp, contrast colour change.



# CONTACT US

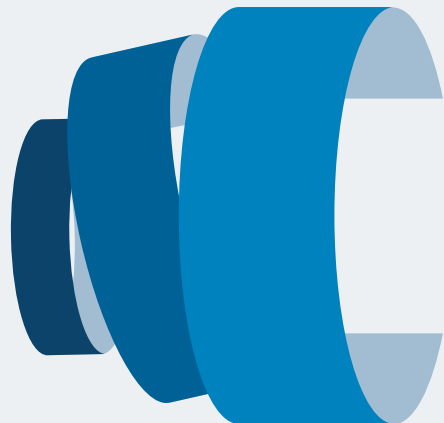
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