Doc. No.:	RGI/IFU-09/5110
Issue No.:	04
Rev. No.:	03
Date	03..10.2022

Romsons®

BILE BAG
(Bile Collection Bag)

REF **GS-5110 (350ml)**

℞ ONLY

INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic , Phthalate Free, Sterile, Single Use.

⚠ **Caution:** Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Device Description :.Device Consist of a PVC Bag (Capacity 350 ml). Bile Bag has Graduation from 25 ml to 350 ml as per case. These graduations are only for indicative purpose. Bile Bag on its proximal end consists of an Inlet Tube. This tube is followed by a Non Return Valve (NRV) to disable accidental backflow of fluid attached to a double tapered step connector this connector get fixed to the distal end of the T-tube Bile Drainage adaptor .Distal end of the Bile Bag consist of a outlet tube attached to a one quarter turn open and close adaptor . Which helps in instant drainage of collected fluid in the bag .Bile Bag consists of fur eyelets at the top and two eyelets at the bottom to enable Hanging / Attachment of Bile Bag .
Population of Use: Adult & Paediatrics.
Intended User : To be administered by an expert qualified medical professional.
Intended Use : Intended for the collection of drained bile. Maximum use period not more than 7 days
Preferred Route of Administration: Attached to the T-Tube(Kehr's T-Tube)
Contents : Sterile, One Unit in a Peel Open Pack.

Size : Capacity-350ml.

Material of Construction : PVC, PP, PE, MB.

Storage : Store in a cool & dry place.

Indications : Bile Duct Drainage, percutaneous drainage, percutaneous trans hepatic biliary drainage, trans hepatic gallbladder drainage, subhepatic collection, etc.

Contraindications : Use in patient with a known allergic reaction to any of the product components , Massive ascites, multiple intrahepatic obstructions, bleeding diathesis, etc.

Potential Complications / Risks : Acute biliary sepsis, persistent hyperbilirubinemia, malignant biliary obstructions, acute hemobilia.

Warnings : This device is intended for Single use only.
DO NOT resterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
Do not put the Device to Use after the Use by Date or Date of Expiry.
Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
Contamination and / or limited functionality of the device may lead to injury, illness of the patient.

Precautions :
(i) Check the integrity and functionality of the Bile Bag before use. Do not use if the Unit Pack is open or damaged.
(ii) Determine patient's condition and vitals status During device application / Operation.
(iii) Conduct procedure under strict surgical protocol and ensure complete asepsis.
(iv) Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
(v) Do not Re-sterilize. Do not Re-use. Single use only.
(vi) Do not put the Device to Use after the Use by Date or Date of Expiry.

Adverse Events : Biliary leakage, Biliary obstructions, Bag dislodgement from connector, Bile Spillage & contamination / infection, etc.

General Instructions :
To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration Dispose the device after use as bio-medical waste as per applicable laws.

Use Instructions :
(1) Check the packing carefully, if found damaged, torn or pierced discard the piece.
(2) Wash up and scrub hands and preferably use pre sterile protective gloves.
(3) Peel open the pack & draw out the device with care.
(4) Close & Close the Bottom Outlet of the Bile Bag.
(5) Connect the drainage tap to the Kehr's / Ryles Connector / Wide Bore double tapered connector.
(6) To drain, Open the drainage tap & then close after use.
(7) Discard the Bile Bag after Single Patient Use.

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CE 2460

Basic UDI DI : 8902120F005SK

REF	**Catalogue Number**	MD	**Medical Device**		**Donot Re-use**		**Consult Instructions for Use**
LOT	**Batch Code**	IN	**Country of Manufacture**		**Do Not Re-sterilize**		**Keep away from sunlight**
	Date of Manufacture	STERILE EO	**Sterilized Using Ethylene Oxide**	UDI	**Unique device Identifier**		**Keep Dry**
	Use by date		**Non-pyrogenic**		**Do Not Use if Pack is Damaged and consult Instructions for Use**		**Caution,**
	Non Return Valve	EC REP	**Authorized Representative in the European Union**		**Single Sterile barrier system**	10 °C 40 °C	**Temperature Limit**
	Manufacturer						