

Instruction for Use

Stone Screen

Device Description

Stone Screen is a urine straining device. It is a collapsible plastic strainer cup designed for both men and women and includes a nylon screen at the bottom of the cup for stone capture. Once the stone is captured, it can be placed in the storage space under the lid and saved for analysis.

Family	Height (mm)	Diameter(mm)	Diameter (Mesh-mm)	Color
Stone Screen (STS)	69.3	57	36.3	White/ Half white(Ivory)

Intended Purpose

Stone Screen kidney stone collection cup aids in the capture of renal calculi and for use in patients attempting to pass stones following extracorporeal shock wave lithotripsy. Intended for Use in patients with Kidney Stones and to store the stones for analysis.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Kidney stones (renal calculi) in patients attempting to pass stones naturally
- Patients undergoing extracorporeal shock wave lithotripsy (ESWL) for stone fragmentation
- Conditions requiring collection and storage of passed stones for further laboratory analysis

Performance Characteristics of the Device

Stone Screen aids by capturing the renal stones/foreign materials for the later examination. It helps in the further analysing of the stones for more serious health problems by catching the stones in the mesh during urination. Rinseable to accommodate several uses.

Indications

Stone Screen is used to store the stone collected from patients diagnosed with kidney stones and stones in other organs, such as gall bladder or liver for future analysis.

Contraindications

No Specific Contraindications.

Precautions & Warnings

Carefully read all instructions for use and product labelling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment.
- The stone screen should be rinsed after each voiding and stored for additional use as needed. This device can be used numerous times if the inner screen is intact.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- If any component is found damaged or unsuitable for use, do not use. Contact "Distributor" for replacement.

Warning

- Follow your doctor's instruction on how to handle the stone or stone fragments recovered during urination.

Intended Patient Population

- Used for all age groups diagnosed with Kidney Stone.

Shelf-life

Stone Screen is a non-sterile device, hence there is no specific shelf-life for the product and is re-usable.

Sterility

- The Stone Screen are supplied non-sterile and can be re-used once thoroughly cleaned by single patient.
- The device can be re-used until the mesh/screen is intact.
- The Stone Screen are packed single.

Directions for Use

Suggested instructions for using Stone Screens:

- Open the package at the Chevron Side ('V' Notch) of the pouch.
- Remove the lid from the stone screen.
- Extend the cup to its full telescope position.
- Urinate through the centre of the cup.
- After urination, observe the inner screen for urinary stones.
- Remove stones or stone fragments and place in the holding area under the stone screen lid.
- Clean the device as per instructions and replace the lid and store for additional use.




















Disposal Instructions

- Dispose of all equipment in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Cleaning Instructions

- Rinse the Stone Screen in cool, clean water using a suitable disinfectant after each use.

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Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		Unique Device Identifier		Do not re-sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		



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Bibliography

- MDCG 2019-15 rev 1- Guidance Notes for Manufacturers of Class I Medical Devices
- EU MDR 2017/745 Regulations
- EN ISO 15223-1:2021 – Medical Devices- Symbols to be used with information to be supplied by the manufacturer- Part 1: General Requirements
- EN ISO 20417:2021 – Medical Devices -Information to be supplied by the Manufacturer