



**ROTHBAND**

PATIENT POSITIONING

## **INSTRUCTIONS FOR USE**

SURGICAL DRAPE SUPPORT

VERSION 1.0



**UK  
CA CE**

## Table of Contents

<b>INTRODUCTION .....</b>	<b>3</b>
<b>INTENDED USE.....</b>	<b>3</b>
<b>CE COMPLIANCE .....</b>	<b>3</b>
<b>CAUTIONS AND WARNINGS.....</b>	<b>4</b>
<b>POSITIONING RECOMMENDATION .....</b>	<b>5</b>
<b>CLEANING INSTRUCTIONS.....</b>	<b>6</b>
<b>CONTACT DETAILS .....</b>	<b>6</b>

## INTRODUCTION

The Surgical Drape Support is a simple, lightweight, radiolucent device to keep surgical drapes off a patient's face during procedures such as central line placement.

These Instructions cover the following models:

<b>PRODUCT</b>
<b>Surgical Drape Support</b>

## INTENDED USE

The Rothband Surgical Support range has been designed for use with medical imaging equipment.

The SDS has not been designed to bear weight, other than that of a single surgical drape.

## CE COMPLIANCE

The SDS range complies with MDR (EU) 2017/745 concerning medical devices (class I) and has been designed and manufactured to comply with the following standards:

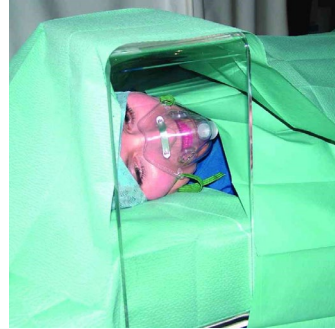
Standard	Description
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.



## CAUTIONS AND WARNINGS

- There are no special skills required to use this positioning aid.
- The medical professional is responsible for applying his/her best medical judgment when positioning a patient using the SDS.
- The SDS aids is suitable for continuous use.
- Not suitable for sterilisation.
- Do not place device on or near a heat source.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Intended for professional healthcare facility environments where operators with medical training are continually available when patients are present.
- Do not use abrasive cleaners, please see page 5 for the correct cleaning instructions.
- Do not place heavy objects on the SDS.
- Be aware when using contrast media, as staining may cause radiographic artefact.
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

## POSITIONING RECOMMENDATION



The Surgical Drape Support is a simple, lightweight, radiolucent device to keep surgical drapes off a patient's face during procedures such as central line placement.

The SDS reduces the feeling of claustrophobia (for the patient) and allows un-interrupted observation of the patient during the procedure.

1. Position SDS with longer arm under mattress/pillow behind patient's head, resting on a firm level surface such as the examination table.
2. The weight of patient's head will anchor the support in position.
3. For right sided access position so that patient's face is looking through the upright section of support.
4. Reverse the procedure for left-sided placement.
5. Place sterile sheets over support.

## CLEANING INSTRUCTIONS

Use a solution of mild soap or detergent or disinfectant\* in hand-hot water.

Apply using a soft cloth & light pressure to prevent swirls.

Rinse off with clean water and dry by blotting with a soft cloth/towel.

WSR Medical Solutions Limited recommend Envirolex hard surface cleaner.

\*DO NOT Use Solvents or Alcohol based cleaning products.

DO NOT Use any scouring materials/pads to clean the product as this will damage the surface finish.



Cross contamination is a major hazard to patients. The SDS should therefore be cleaned in between patients.

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## CONTACT DETAILS



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