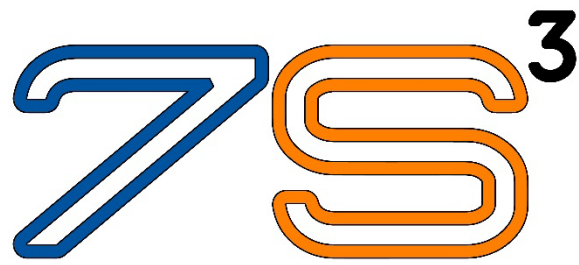


User Guide

Instruction Manual

Modular Cricoid Skills Trainer w/Suturing Kit

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7-SIGMA Simulation Systems



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Table of Contents

1	Introduction	3
2	Modular Construction	4
3	How to Use.....	5
4	Care and Maintenance	6
5	Airway Lubricant - Usage Instructions	7
6	Limited Warranty	8
7	Contact Information	10

1 Introduction

1.1 Realistic Procedure

The 7-SIGMA Simulation Systems Modular Cricoid Skills Trainer is unparalleled in its attention to the details crucial to realistically simulating intubation, ensuring that medical practitioners receive training that translates into superior patient care. The 7S3 Modular Cricoid Skills Trainer pairs faithful replication of appearance and feel making this trainer vital tool for instilling the skillsets, knowledge, and confidence necessary for successful cricothyrotomy and suturing. The 7S3 Modular Cricoid Skills Trainer is the superior choice for developing best practices to safely perform a cricothyrotomy or suture.

1.2 Quality

Our name, 7-SIGMA, says it all. Our strategy is to strive for an error free process. We pursue this goal through feedback from the market, attention to product performance, and continuous process improvement. Our Quality Management System includes:

2 Modular Construction

Our Cricoid Skills Trainer is modular. Removable and interchangeable parts allow for numerous training configurations as well as easy replacement and cleaning without the use of tools.

2.1 Cricothyrotomy Component

The cricothyrotomy module offers a jaw line for reference of location. In addition, a trachea module is provided that allows for the proper tactile feel of the thyroid cartilage and cricoid ring. This partnered with our 7S³ skin strips allow for realistic simulation performing a cricothyrotomy procedure. (Figure 1)



Figure 1

2.2 Suturing Components

The suturing module offers a contour for a realistic contour for the suturing to be performed on. This partnered with our 7S³ skin strips allow for realistic simulation of a suturing procedure. . (Figure 2,)



Figure 2

3 How to Use

3.1 Cricothyrotomy

Preparing for the cricothyrotomy module.

1. If the suturing module is attached, slide it off and remove. The handle should be in an upward position.
2. Slide the cricothyrotomy module onto the device aligning the slides with the slots on the module.
3. Take one of the tracheas and insert the balloon into the bottom hole of the trachea.
4. Apply five drops of lubricant into the trachea.
5. Insert the trachea through the hole that creates the jawline, the top of the trachea piece should rest against the ledge near the jawline.
6. Insert a skin strip through the two hoops on the sides of the device.
7. The handle can now be lowered to lock things in place. It is now ready for use.
8. Lift the handle up and slide the strip over for the next incision.

3.2 Suturing

Preparing for the suturing module.

1. If the cricothyrotomy module is attached, slide it off and remove. The handle should be in an upward position.
2. Slide the suturing module onto the device aligning the slides with the slots on the module.
3. Insert a skin strip through the two loops on the side of the device.
4. Lower the handle to lock the module in place. The device is now ready to use.
5. The handle can now be lowered to lock things in place. It is now ready for use.
6. Lift the handle up and slide the strip over for the next incision.

4 Care and Maintenance

Care, Clean and Disinfecting Instructions for the 7S³ Modular Cricoid Skills Trainer.

7-SIGMA Simulation Systems is not responsible for routine care and maintenance of your product.

4.1 Care

- a) Conduct training sessions on a clean, hard, and stable surface.
- b) Keep ink pens, markers, any other staining devices, and liquids away from the Trainer.
- c) Store in a clean, room temperature area.
- d) The tracheas are a semi disposable item, meaning that over time they will need replacing. *(The cartilage material will get compromised due to all the cuts that it receives.)*

4.2 Cleaning

- a) After each use, clean external surfaces with a mild soap and tap water solution. Rinse by wiping with soft cloth, moistened with clean tap water. Gently dry the Trainer with a clean, lint free cloth.
- b) To clean the trachea, remove it from the Skills Trainer and wash with warm soapy water. Do this gently to ensure the longevity of the trachea.

4.3 Disinfecting the Airway

After prolonged use, disinfect the airway with a bleach and water solution after performing the above soap and water cleaning process.

Note: The bleach and water solution, rinsing, and drying process is specified by the Center for Disease Control at <https://www.cdc.gov/disasters/bleach.html>.

5 Airway Lubricant - Usage Instructions

Welcome to your new **7-SIGMA Simulation Systems (7S³) Modular Cricoid Skills Trainer**. To achieve the best experience with our Skills Trainer, we recommend the followings:

5.1 Preparing the Airway

To prepare the Torso Airway Trainer for a procedure or class, please take a few moments to lubricate it properly.

1. Put 4-6 squirts of 7S³ Lubricating Spray down the trachea and smear it around with your finger.
2. Take an endotracheal tube and spray it wipe our lubricating spray covering the balloon.

If you have any questions regarding the use of the **7S³ Modular Cricoid Skills Trainer**, please do not hesitate to contact us.

Technical Support

Email: technicalsupport@7-sigma.com

Phone: 1.888.722.7224

6 Limited Warranty

6.1 Covered by This Limited Warranty

- Under this Limited Warranty, 7-SIGMA warrants the product to be free from defects in materials and workmanship arising under proper and normal use, for a period of one (1) year from the date of purchase.
- If the product proves defective due to improper materials or workmanship, 7-SIGMA will, at 7-SIGMA's discretion and without charge for labor or parts, repair or replace the product or its defective parts upon the terms and conditions set out below. 7-SIGMA shall have sole discretion as to which of these remedies it shall provide.

6.2 Not Covered by This Limited Warranty

- This Limited Warranty does not cover any damage, deterioration, or malfunction resulting from any alteration, modification, improper or unauthorized repair or maintenance, misuse, abuse, accident, neglect, improper storage, or any other cause which does not relate directly to a defect in materials and/or workmanship of this product.
- This Limited Warranty does not cover normal wear and tear, staining, discoloration or cosmetic irregularities which do not impede or degrade product performance.
- This Limited Warranty does not cover consumables provided with the product.
- The Limited Warranty does not cover, and 7-SIGMA shall not be responsible for, shipping damage or damage caused by mishandling by the freight carrier and any such damage is the responsibility of the freight carrier.

6.3 Conditions

- Only the original purchaser of this product is covered under this Limited Warranty. This Limited Warranty is not transferable to subsequent purchasers or owners of this product. The original invoice or sales receipt must be presented together with the defective product to invoke this Limited Warranty. 7-SIGMA reserves the right to refuse service under this Limited Warranty if the above documentation/information cannot be presented or if the information contained in it is incomplete or illegible.
- If 7-SIGMA elects to replace or repair the defective product, the replaced or repaired product will be warranted for the remainder of the Limited Warranty period applicable to the originally shipped product, but the Limited Warranty shall not be extended beyond the original Limited Warranty period.

- This Limited Warranty will not reimburse nor cover the damage resulting from adaptations or adjustments which may be made to the product, without the prior written consent of 7-SIGMA, in order to conform to the national or local technical or safety standards in force in any country other than the ones for which the product was originally designed and manufactured.
- This Limited Warranty will not apply if the serial number on the product has been altered, deleted, removed or made illegible.
- 7-SIGMA's sole and exclusive obligation and the original purchaser's exclusive remedy under this Limited Warranty is 7-SIGMA's repair or replacement of the defective product or a credit for the purchase price of the defective product.

TO THE MAXIMUM EXTENT PERMITTED BY LAW, THIS LIMITED WARRANTY AND THE REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES AND CONDITIONS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. TO THE MAXIMUM EXTENT PERMITTED BY LAW, 7-SIGMA SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, AND ANY REPRESENTATION OR WARRANTY ARISING BY USAGE OF TRADE, COURSE OF DEALING OR COURSE OF PERFORMANCE. 7-SIGMA'S TOTAL LIABILITY FOR ANY CLAIM OR DAMAGE ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, SALE, DELIVERY OR USE OF THE PRODUCTS WILL BE LIMITED TO PROVEN DIRECT DAMAGES, NOT TO EXCEED THE PURCHASE PRICE OF SUCH PRODUCTS. IN NO EVENT WILL 7-SIGMA BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING, WITHOUT LIMITATION, ANY CLAIM FOR LOSS OF ACTUAL OR ANTICIPATED REVENUES OR PROFITS.

6.4 How to get Warranty Service

All defective products must be returned with a Return Merchandise Authorization Number (RMA) which customer must request from 7-SIGMA Simulation Systems. Customer must include the following information:

- Proof-of-purchase in the form of the dated purchase receipt
- Model number of the Defective Product
- Serial number of the Defective Product
- Detailed description of the defect
- Shipping address for return of the repaired or replacement product

Requests for RMAs should be directed to: **customerservice@7-sigma.com** or **1-888-722-7224 (TF)**

7 Contact Information

7.1 Phone & Fax

Toll Free:

Phone: 1.888.722.7224

Customer Service – Option 1

Technical Support - Option 2

Fax: 1.844.898.4755



7.2 Email

Technical Support

technicalsupport@7-sigma.com

Customer Service

customerservice@7-sigma.com

7.3 Address

7-SIGMA, Inc.

3101 Louisiana Ave. North / New Hope, MN 55427

<http://www.7-s3>

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