	<h1>Training Specification</h1> <p>COOK® Urological</p>		
Title:	Training Guidelines And Qualification For Balloon Folding Procedures		
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1.0 PURPOSE

To train and qualify operators to fold balloons.

2.0 SCOPE

This procedure is required for all employees who fold balloons. All operators are required to be trained on folding procedures for each inspection specification.

This procedure qualifies employees to fold balloon using the different techniques required. This qualification will occur once, unless retraining is deemed necessary by management or new techniques are added.

3.0 REFERENCES

- 3.1 [SI-421](#) Manual Balloon Folding
- 3.2 [SI-285](#) Balloon Folding
- 3.3 Inspection Specifications

4.0 DEFINITIONS

None

5.0 EQUIPMENT/MATERIALS

Equipment that may be necessary is listed below. Refer to inspection specification for equipment requirements for each part number.

5.1 Smooth Jaw Pliers


- 5.1.1 Used to smooth out the folds, decrease sharp edges and ease application of folding sleeve. Use pliers on folding sleeve only, not directly on the balloon or on the cuff of the balloon. Do not use pliers directly on the marker bands, because this could weaken or damage the balloon material. Do not clamp the pliers too tight around the balloon causing damage.

5.2 Stylet

- 5.2.1 Place the stylet in the inner lumen of the catheter to aid in holding the catheter ID/shape while the balloon is being folded. This prevents the lumen from collapsing.

5.3 Medical Fluid

- 5.3.1 Some folding sleeves are very tight over the balloon, so medical fluid can be used to aid in application of the folding sleeve in the balloons that allow it. Some balloons cannot have medical fluid sitting on their surface therefore it cannot be used. Only use medical fluid on balloons that specifically state its use for folding.

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5.4 Heated Fluting Fixture

- 5.4.1 A fixture that uses heat and pressure to fold the balloon using more than 2 folds so the balloon can meet the minimum OD requirements after being folded for ease of customer use.

6.0 RESPONSIBILITIES

- 6.1 OJT/Group Leader/Supervisor/qualified folder are responsible for training and verifying the product and filling out the forms/signing them. Training shall be documented in the employees training file.

7.0 PROCESS PARAMETERS (Independent Variables):

The ability of the employee to use the required tools to fold a balloon.

8.0 PROCESS OUTPUTS (Dependent Variables):

Properly folded balloons.

9.0 PROCEDURE


- 9.1 Training will take place following [SI-421](#) and/or [SI-285](#) procedures and Inspection Specifications. Trainer is to go over the topics in the checklist in Section 1 of [CT04-Form 01](#). The operator is allowed to ask questions of the trainer. Once the operator/trainer feels comfortable with the technique, the trainer proceeds to Step 9.2.

- 9.2 Trainee is to answer all exam questions in Section 2 of [CT04-Form 01](#) using the corresponding SI. Upon completion, trainer is to grade the exam accordingly.

- 9.2.1 If all questions are answered correctly, trainer proceeds to Step 9.3
- 9.2.2 If all questions are not answered correctly, trainer is to go over incorrect answers with the trainee, and re-administer the exam on a new form.

- 9.3 Trainee shall then fold the balloons provided by the trainer. Trainer will ensure that the balloons used for training have been through QC inspection and leak test process. This should be done prior to trainee qualification to verify there are no defects present prior to folding and testing for the qualification.

- 9.3.1 Trainee is to build any of the balloons that reference [SI-421](#) and [SI-285](#) for the procedures specified. The assembler to be qualified will fold a minimum of 14 balloons. Multiple work orders on multiple dates may be used. Additional balloons may be folded for the qualification and attached to the other sheets. Part numbers required to be qualified on the specific SI/procedure:

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- 9.3.1.1 [SI-421](#) Manual Balloon Folding Procedure A, Part # = any that reference [SI-421](#) procedure A, minimum of 14 balloons, data to be recorded in Section 3 of [CT04-Form 01](#).
- 9.3.1.2 [SI-421](#) Manual Balloon Folding Procedure B, Part # = any that reference [SI-421](#) procedure B, minimum of 14 balloons, data to be recorded in Section 4 of [CT04-Form 01](#).
- 9.3.1.3 [SI-285](#) Balloon Folding, Part # = any that reference [SI-285](#), minimum of 14 balloons, data to be recorded in Section 5 of [CT04-Form 01](#).

9.4 The trainer shall perform the following inspections and record the results for training on each procedure in the corresponding section as noted in Step 9.3.1.

9.4.1 Visual Inspection:


9.4.1.1 Inspect exterior of folding sleeve after being applied to the balloon for any signs of damage and verify it is installed correctly per applicable procedure ([SI-421](#) Manual Balloon Folding Procedure A or B/[SI-285](#) Balloon Folding Procedure). Remove folding sleeve carefully. Inspect balloon and glue bonds for any signs of damage, weakening and sharp edges. Verify the balloon was folded correctly and in the correct direction per applicable SI. This will result in either Pass or Fail results.

9.4.2 Leak Test

9.4.2.1 The QSpec for leak testing the product shall be performed according to each individual product's QSpec. Inspect the balloon while inflated for signs of weakening, damage or leaks in the material. The balloon shall hold the volume of air required in the specification that the balloon is currently tested to prior to folding. This will result in either Pass or Fail results.

9.5 If the balloons pass both inspections the trainer who inspected the balloons will re-fold the balloons and they can be sent to the next processing step. Trainer and trainee shall fill out Section 6 of [CT04-Form 01](#) and file the form in the trainee's training file once all training is complete.

9.5.1 If any part fails, the operator is not qualified to fold balloons. The QC manager and engineering shall be notified. They will determine if/how the person should be retrained and qualified.

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10.0 Acceptance Criteria

- 10.1 All exam questions must be answered correctly
- 10.2 All training topics must be covered.
- 10.3 All evaluated balloons must have 0 defects in both visual inspection and leak test criteria for the folder to become qualified. The following confidence statement can be made: with 95% confidence, the process is at least 80% reliable (per SOP 21.1.1, the confidence interval can be made based off the sample size selected of 14).

11.0 DOCUMENTATION

- 11.1 [CT04-Form 01](#)
- 11.2 [CT04 ExamA](#)