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|  | <h1>Training Specification</h1> <h2>COOK® Urological</h2> | | |
| Title: | Balloon Folding Qualification Exam/Tests | | |
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SECTION 1 - TRAINING CHECKLIST

Directions: Please cover the following topics with trainee. Upon completion of each topic, put a check mark in the box. At the completion of the training, please sign and date at the bottom of the page.


| Folding | |
|---------|---------------------------------------------------------------------------------------------------------------------------------|
| | Use of the smooth jaw pliers, which products they can be used on, proper technique, and where not to use the pliers |
| | Which products require a stylet and where the stylet size is located on the Inspection Specification. |
| | When and how to use the medical fluid as well as which products it can be used on to aid in applying the folding sleeve |
| | Correct folding direction and technique with the catheter centered between the flaps |
| | Do not twist the folding sleeve onto the balloon (Unless spec states to do so), this can damage or weaken the balloon material. |

Trainee: _____

| Print Name | Signature | Date |
|------------|-----------|------|
| | | |

Trainer: _____

| | | |
|------------|-----------|------|
| Print Name | Signature | Date |
|------------|-----------|------|

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SECTION 2 - WRITTEN EXAM

Trainee: _____
Print Name Signature Date

Directions: Please answer the following questions. Feel free to use your SI's, drawing and QC document to help you answer them. Record these document numbers at the bottom of the page.

1. What SI is used for manually folding balloons? _____
2. How many procedures are on that SI? _____
3. What SI is used for folding balloons with the heated fixture? _____
4. Will training for balloon folding occur for each employee even if they are qualified to fold balloons?

Graded By: _____ Exam Score: _____
Print Name Signature Date

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SECTION 3 - INSPECTION SI-421 PROCEDURE A

Directions: Please fill out the following table according to the results of the inspection.


Part # _____ Assembler # _____ SI-421 Procedure A

| Sample # | Pass/Fail visual check | Pass/Fail leak test at _____ psi per Qspec | WO # | Date | Comments |
|----------|------------------------|-----------------------------------------------|------|------|----------|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |

Did all the folded balloons pass visual inspection and leak test? YES NO

Inspector: _____
Printed Name Signature Date

Overall Result: _____

| | | | |
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SECTION 4 - INSPECTION SI-421 PROCEDURE B


Directions: Please fill out the following table according to the results of the inspection.

Part # _____ Assembler # _____ SI-421 Procedure B

| Sample # | Pass/Fail visual check | Pass/Fail leak test at _____ psi per Qspec | WO # | Date | Comments |
|----------|------------------------|-----------------------------------------------|------|------|----------|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |

Did all the folded balloons pass visual inspection and leak test? YES NO

Inspector: _____ Overall Result: _____
 Printed Name Signature Date

| | | | |
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SECTION 5 - INSPECTION SI-285

Directions: Please fill out the following table according to the results of the inspection.

Part # _____ Assembler # _____ SI- 285

| Sample # | Pass/Fail visual check | Pass/Fail leak test at _____ psi per Qspec | WO # | Date | Comments |
|----------|------------------------|-----------------------------------------------|------|------|----------|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |

Did all the folded balloons pass visual inspection and leak test? YES NO

Inspector: _____ Overall Result: _____
 Printed Name Signature Date

SECTION 6 - APPROVAL

The above specified assembler has adequately completed and passed all listed requirements and is hereby trained to perform the specified process.

Trainee: _____
 Print Name Signature Date

Trainer: _____
 Print Name Signature Date