COOK MEDICAL	**Training Specification** COOK® Urological
Title:	**Training Guidelines for Bonding Closed-End Flexi-Tip Catheters on Equip ID 1180**

Document Number: CT07	Original Date: 20Aug2013
Version Number: 5	Effective Date: 15Aug2016
CR Number: CIN-16-2650	Checked By: MES 15Aug2016

1.0 PURPOSE

The purpose of this training document is to verify the competency of operators in the process of bonding Closed-End Flexi-Tip Catheters using Equip ID 1180.

2.0 SCOPE

This procedure affects the assembly of Flexi-Tip bonded catheters as described by drawing **C4576** and assembled by MI **021103**. The device is manufactured in the Catheter Department and is part of process validations using Equip ID 1180.

3.0 REFERENCES

3.1 **021103** MI Flexi-Tip Ureteral Catheter

3.2 **021103** QCIS Flexi-Tip Ureteral Catheter

3.3 **C4576** Drawing Flexi-Tip Ureteral Catheter

3.4 **SI-428** Machine Settings for Saffire Machine/Programming Adjustments

4.0 DEFINITIONS

Tensile Strength – the force required to pull catheter/bond/tip to separation.
Dog Leg – Material displaced during the bonding process, specifically catheter material between the grip and mold allowing the OD to be larger in this location.
Gripper Slide – grips the catheter material, when the pressure is activated it slides the catheter into the mold at the specified pressure setting.

5.0 EQUIPMENT/MATERIALS

5.1 Equipment used on this process is listed on MI **021103** for Flexi-Tip Ureteral Catheter.

5.2 Materials used in this process are listed on the Bill of Materials on drawing **C4576** to the product being produced.

6.0 RESPONSIBILITIES

6.1 It will be management's responsibility to ensure that all operators in the Catheter Department that perform Closed- End Flexi-Tip bonding using Equip ID 1180 shall be trained and tested on the relevant documentation needed to produce these devices.

7.0 PROCESS PARAMETERS (Independent Variables)

- Heat Temperature
- Insert Pressure
- Heat Time
- Insert Delay

7.1 The values of the process parameters have been established through process validations. It is therefore important that operators stay within these parameter ranges to ensure the safety and reliability of the final product.

- The amount of heat applied is determined by the heat temperature and heat time. The insert delay determines how long into the heat time the insert pressure is initiated to push the catheter and tip material together. During the bonding procedure there are five possible adverse effects that could occur:
    1. If not enough heat is transferred for a sufficient amount of time the product may not completely bond, bond at all leaving the tip inside the mold or may have a weaker bond.
    2. If too much heat is added the materials may not bond in a smooth manner or may create a weak spot in the material.
    3. Not enough insert pressure could also create an incomplete bond or a weaker bond.
    4. Too much insert pressure can create thinner walls creating weak spots in the material or bonds.
    5. Too much pressure can also create a “dog leg” on the catheter body, not allowing it to meet the maximum OD requirement.

7.2 The catheter material must be completely butted up against the tip material before starting the cycle; if it is not adequate pressure may not be applied to produce the bond. When the cycle is activated the gripper slide should not bottom out against the mold (there should be a space between the mold and the gripper slide), if the gripper slide is up against the mold less pressure than specified may be applied potentially decreasing the bond strength.

7.3 From time to time and/or lot to lot it may be necessary to adjust one or more settings to meet the QC acceptance criteria (**021103**). Refer to **SI-428** for the validated range of parameters by parameter and French size.

8.0 PROCESS OUTPUTS (Dependent Variables)

8.1 Catheter to tip bond tensile strength (**SI-44A**)

9.0 PROCEDURE

9.1 Trainer will review process parameters and outputs as stated above with the trainee. Allow time to answer any questions the trainee may have.

9.2 Trainer will explain how to set-up the equipment required by MI **021103** for the process by covering the following training points:

9.2.1 Identify the location and demonstrate the function of the On/Off switch, parameter selection, start button/foot pedal, Temperature display, heat time display, and pressure regulators along with which regulator is used for which output. Refer to **SI-428**.

9.2.2 Identify the equipment ID number, calibration tag and calibration due date.

9.2.3 Demonstrate how to identify and change the molds and grippers.

9.3 Trainee must complete Section 1 of **CT07-Form_01**. Upon completion, the trainer is to check all answers and grade them accordingly.

9.3.1 If all questions are answered correctly, the trainer is to print his/her name, sign, and date the appropriate line of Section 1 of **CT07-Form_01**.

9.3.2 If any question(s) are not answered correctly, trainer is to go over incorrect answer(s) with the trainee, and re-administer the exam on a new form until the trainee answers all questions correctly. Attach the new form to the old form and keep both for training records.

9.4 The trainee proceeds to Section 2 of **CT07-Form_01** and must bond 10 closed-end flexi-tip catheters according to specifications using the required equipment for the product being built.

9.5 Once the bonding has occurred, the trainer proceeds to section 3 of where the product will be inspected by QC according to **021103** in accordance with **SI-44A** for tensile testing.

9.5.1 If the bonded catheters do not pass inspection, retraining or additional practice is required, as determined by the trainer. Section 2 and 3 of **CT07-Form_01** and sends the results back to the catheter department.

9.6 After sections 1 through 3 of **CT07-Form_01** have been completed, the trainer must:

9.6.1 Verify the information in **CT07-Form_01** is documented correctly.

9.6.2 Verify the bonded catheters passed inspection criteria listed in Section 3.

9.6.3 Complete Section 4 of **CT07-Form_01**.

9.6.4 Completed CT document and attachments shall be kept permanently in trainee's training file.

10.0 ACCEPTANCE CRITERIA

10.1 All exam questions must be answered correctly.

10.2 All parts built must pass the tensile test minimum per **SI-44A**.

11.0 DOCUMENTATION

11.1 **CT07-Form_01** shall be filed in trainee's training file.

COOK MEDICAL	**Controlled Training Procedure Form** COOK® Urological
Title:	**Training Guidelines for Bonding Flexi-Tip Catheters on Equip ID 1180**

Document Number: CT07-Form_01	Original Date: 20Aug2013
Version Number: 5	Effective Date: 15Aug2016
CR Number: CIN-16-2650	Checked By: MES 15Aug2016

SECTION 1 – WRITTEN EXAM

Trainee: _____
Printed Name Signature Date

Directions: Please answer the following questions. Feel free to use reference specifications to help you answer them.

Trainee must correctly answer the following questions:

1. What parameter setting is used for 5fr bonding on Equip ID 1180? _____
2. When changing the heat time what needs to be added to the seconds listed on the specification when entering it into the machine?
   _____
3. How are closed end tips loaded into the mold? _____
4. True/False The catheter does not need to be butted up against the tip material in the mold.
5. True/False The temperature can be changed only within the range specified on the specification.
6. Explain to trainer how each of the process parameters affect the process output(s). Trainer: Initial if completed correctly_____

   MI _____ SI_____ DWG_____

Graded by: _____Overall Result (Pass/Fail)
Printed Signature Date

SECTION 2 – MANUFACTURING

Manufacture ten (10) partial assemblies (any French size, bonding the tip to the catheter only), ensuring the tip is bonded to the catheter per the corresponding specifications. Write the RPN of the product built on the next section.

SECTION 3 – QC INSPECTION

RPN_____

Directions: Test the tensile strength in accordance with SI-44A. Attach the tensile test results.

Inspector: _____ Overall Result: (Pass / Fail)

Printed Name Signature Date

SECTION 4 – APPROVAL

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

Trainer: _____

Printed Name Title Signature Date

Trainee: _____

Printed Name Title Signature Date