	Controlled Training Procedure COOK® Incorporated	
Title:	Training Procedure for Assembly of Perc NGage	
<small> WARNING - CONFIDENTIAL PROPRIETARY PROPERTY This document is owned by COOK Medical. It contains confidential proprietary trade secret information and must not be copied. The document and the information it contains can be used only by the recipient for the specific use for which it was requested. All other use is strictly prohibited. This document must be returned to COOK Medical immediately upon request by COOK Medical. By possession of this document, the possessor expressly agrees to comply with these terms. © COPYRIGHT COOK® Incorporated 2014 </small>	Document Number: CT09	Original Date: 24March2014
	Version Number: 2	Effective Date: 02Sep2014
	CR Number: CIN-14-2692	Checked By: MES 02Sep2014

1.0 PURPOSE


The purpose of this training document is to verify the competency of operators in the assembly of the Perc NGage (NGRE-100038), especially in the validated processes of gluing the PINT tubing and basket wires to the inside diameter of the 14GRW cannula and crimping the 17GHW cannula during the production of the Perc NGage Nitinol Stone Extractor.

2.0 SCOPE

This procedure affects the assembly of the Perc NGage Nitinol Stone Extractor as described by drawings [R6713](#) and [E6712](#) and assembled by [NGRE MSPEC](#). The device is manufactured in the Baskets Department of Cook Inc. Spencer.

3.0 REFERENCES

- 3.1 [NGRE MSPEC](#)
- 3.2 [R6713](#) – Perc NGage Subassembly
- 3.3 [E6712](#) – Perc NGage
- 3.4 [Y7019](#) – PINT Gluing Fixture
- 3.5 [Y6986](#) – 17GHW Crimping Jig
- 3.6 [Y4784](#) – Bending Fixture
- 3.7 [Y5304](#) – Air Press Crimping Frame
- 3.8 [Y7053](#) – Wire Forming Cannula Rack
- 3.9 [Y7054](#) – Wire Loading Frame

	Doc. No.: CT09	Controlled Training Procedure Form Training Procedure for Assembly of Perc NGage	Version No.: 2
---	-------------------	---	----------------

4.0 DEFINITIONS

4.1 N/A

5.0 EQUIPMENT/MATERIALS

5.1 Equipment used on this process is listed on [NGRE MSPEC](#)

6.0 RESPONSIBILITIES

6.1 It will be management's responsibility to ensure that all operators in the Baskets department that perform assembly of the Perc NGage shall be trained and tested on the relevant documentation needed to produce these devices.

7.0 PROCESS PARAMETERS

7.1 Amount of glue applied to PINT tubing before application of 14GRW cannula (drops and specified applicator tip)

7.2 Depth of the crimps on the 17GHW cannula

8.0 PROCESS OUTPUTS

8.1 Retention force of the wire and PINT tubing to the 14GRW cannula


8.2 Retention force of the wires to the 17GHW cannula

9.0 PROCEDURE

9.1 Trainer prints their name and title in Section 4 of [CT09-Form 01](#) – do not sign or date until Sections 1-3 are completed

9.2 Trainer goes through the checklist of topics to cover, listed in Section 1. After each topic is covered, the trainer shall put a check mark in the box, indicating that the task has been completed. When all tasks have been completed, the trainer and trainee shall print their name, sign and date at the bottom of the page.

9.3 Once all topics have been covered, the trainee must complete Section 2 of [CT09-Form 01](#) and print, sign, and date his/her name at the top of the page. The trainee must also fill in the MSPEC document and drawing number used to complete the exam in the blanks provided at the bottom of section 2. Upon completion, the trainer shall check all answers and grade the exam accordingly. If all questions were answered properly, the trainee shall proceed to Section 9.4. If all Questions were not answered properly, the trainee is to repeat Sections 9.1 and 9.2.

	Doc. No.: CT09	Controlled Training Procedure Form Training Procedure for Assembly of Perc NGage	Version No.: 2
---	-------------------	---	----------------

- 9.4 Trainer demonstrates assembly of Perc NGage. Trainee must then assemble 10 Perc NGage extractors according to [NGRE MSPEC](#) and its associated drawings, using appropriate equipment and materials as specified in [NGRE MSPEC](#).
- 9.5 Once the extractors have been assembled, the trainer is to assure that the basket operates properly, also remove the inner slide (17GHW cannula), tug on each PINT tube and wire to assure they are secure, and visually inspect the crimps on the 17GHW cannula. If the pieces are not acceptable, the trainer is to show the part to the trainee and explain why it is not acceptable. If all parts are deemed acceptable by trainer, lot is then to be sent to QC. Section 9.4 must be repeated for any parts which are deemed unacceptable by the trainer.
- 9.6 QC procedure: Inspect ten devices per [NGRE QSPEC](#). If any rejects occur, send back to Baskets Department with an explanation of the reason for rejection listed in Section 3 of [CT09-Form 01](#). Section 9.4 must be repeated for any parts which are deemed unacceptable by QC.
- 9.7 If all pieces are considered acceptable, the trainer must then:
- 9.7.1 Verify information in Section 2 of [CT09-Form 01](#) is correct according to information contained in Section 3.0 of CT09.
- 9.7.2 Complete Section 4 of [CT09-Form 01](#).
- 9.7.3 File [CT09-Form 01](#) in the trainee's training file.
- 9.7.4 Properly discard pieces built during the training.

10.0 ACCEPTANCE CRITERIA

- 1.1.1. All training topics must be covered
- 1.1.2. All questions must be answered correctly on exam
- 1.1.3. All parts built must pass QC inspection

11.0 DOCUMENTATION

[CT09-Form 01](#) will be in the trainee's training file