

TRAINING REQUIREMENTS FOR PHYSICIANS USING THE COOK® CHORIONIC VILLUS SAMPLING SET

Chorionic villus sampling (CVS) is a procedure requiring technical dexterity and a well-equipped team. We recommend that CVS be performed only by physicians with adequate training in the technique, at well-equipped centers with experienced support teams.

To assess the adequacy of training, Cook will require a certification from each institution or physician ordering the device to the effect that each physician using the Cook CVS Set is adequately trained. This training must be certified under one of the following categories:

- The physician who will use the Cook CVS Set has performed at least 25 CVS procedures previously, using an approved CVS device.
- The physician who will use the Cook CVS Set will perform at least 25 CVS procedures, using an approved CVS device, under the direction of a physician experienced in the CVS technique before using the Cook CVS Set independently.
- The physician who will use the Cook CVS Set is an investigator participating in the clinical trial of the set and so is exempt from the above training requirements.

Each physician intending to use the Cook CVS Set must complete the Cook CVS Set Training Certification Form below and return it to Cook by one of the following methods: by mail (Cook Medical Incorporated, 1025 Acuff Road, PO Box 4195, Bloomington IN 47402-4195), fax (800.554.8335), or email (customersupport@cookmedical.com).

COOK® CVS TRAINING CERTIFICATION FORM Customer acct. no. _____

In accordance with FDA approval of this device, Cook requires that each physician using the Cook CVS Set receive adequate training prior to use. Please certify that you meet one of the following three qualifying criteria by checking the appropriate box:

- I have performed at least 25 CVS procedures previously, using an approved CVS device.
- I will perform at least 25 CVS procedures, using an approved CVS device, under the direction of a physician experienced in the CVS technique before using the Cook CVS Set independently.
- I am an investigator participating in the clinical trial of the Cook CVS Set and so am exempt from the above training requirements.

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