

20th September 2018

Field Safety Notice

Dear Distributor

This field safety notice has been issued to provide clarification of additional contraindications for the use of BridgeMaster medical's Fetal Scalp Blood Sampling Kit (FBS-AC) and Fetal Scalp Blood Sampling Wands (FBS-W).

The Instructions for Use updated on 20th September 2018 include amended contraindications as follows:

Contraindications

Fetal blood sampling should be avoided and is contraindicated in the following situations:

- Placenta Previa
- Maternal infection (e.g. HIV, hepatitis viruses, herpes simplex virus, anaemia associated infections)
- Inability to identify the fetal presenting part
- Prematurity (birth at less than 34 weeks of gestation)
- Fetal Bleeding Disorders (e.g. haemophilia, anaemia)
- Acute Fetal Compromise (e.g. prolonged fetal bradycardia of >3 minutes)

The updates to the contraindications for use have been made with reference to the RCOG contraindications for Fetal Scalp Blood Sampling procedures.

We request that all of our Distributors for the Blood Sampling Kits and Wands inform their customers of the changes to the contraindications for use of the product.

Please sign the following confirmation of receipt of this Field Safety Notice and that you understand how you need to proceed.

Yours sincerely


Zoe Neal

Managing Director

BridgeMaster medical Limited

I confirm receipt of BridgeMaster medical's Field Safety Notice in relation to updated contraindications for the use of Fetal Scalp Blood Sampling Kit and Fetal Scalp Blood Sampling Wand products. I understand I need to relay this information on to my customers.

Distributor Name: _____

Country: _____

Date: _____