ESSURE® Physician Distribution Agreement

The United States Food and Drug Administration (FDA) has restricted the sale and distribution by Bayer of the Essure System for Permanent Birth Control to users and/or user facilities that provide specific information to patients about the risks and benefits of this device prior to its use in the form and manner specified in the approved labeling. In particular, physicians must convey information using the Patient-Doctor Discussion Checklist - Acceptance of Risk and Informed Decision Acknowledgment (Checklist) which is included in the patient brochure entitled “Patient Information Booklet.”

By signing this document, I agree I will not implant the Essure System in any patient unless and until I have completed all of the following steps with that patient:

- Provided a copy of the Checklist to the patient or the patient’s legal representative;
- Reviewed the Checklist with the patient or the patient’s legal representative;
- Provided an opportunity for the patient or the patient’s legal representative to sign the designated portions of the Checklist; and
- Signed the designated portions of the Checklist to document that I have discussed the benefits and risks of Essure as well as the benefits and risks of available alternatives, and have addressed all questions from the patient.

Signature*: __________________________________________________________

Printed Full Name (First, Middle, Last)*: ____________________________________

State License (State, Number)*: _____________________________________________

Prescriber NPI# or DEA#: _________________________________________________

Date (MM/DD/YYYY)*: ____________________________________________________

* Required fields have been marked with an asterisk

Return completed form to Bayer via fax 862-404-3036 or email EPDA@bayer.com