# How FDA Requires that Information be Provided to Patients

The sale and distribution of the IDEAL IMPLANT Structured Breast Implant is restricted to surgeons and facilities that provide information to patients about the risks and benefits of this implant prior to surgery in the following manner, as required by FDA:

1. The surgeon provides the patient with the Patient Decision Checklist that is in the Patient Information Booklet.

2. The Patient Decision Checklist is reviewed by the surgeon with the patient to assure that the patient understands the risks, benefits, and other information associated with implantation of this implant.

3. The patient is given an opportunity to initial and sign the designated portions of the Patient Decision Checklist to document that the patient has been informed of the risks, benefits, and other information associated with implantation of this implant and has decided to proceed with implantation of this implant.

4. The designated portion of the Patient Decision Checklist is signed by the surgeon to document that the surgeon has discussed the risks and benefits of this implant as well as the risks and benefits of available alternatives and has addressed all questions from the patient.

To document surgeon compliance with the FDA requirements, provide a copy of the signed checklist to the patient and place a copy in their medical record.

IDEAL IMPLANT®