Final

Consent to Participate in a Research Study

Study Title:	Pilot Study of Safety and Efficacy of 2.5% ADHESIABLOC® Gel to Reduce Adhesions Following Peritoneal Cavity Surgery
Sponsor:	Device Med-Systems
Protocol Number:	P-D015
Principal Investigators:	Jonathan Q. Kruger, M.D.
Address:	Device Med-Systems 5746 Union Mill Road Clifton, Virginia 20124
Telephone:	[redacted]
After Hours:	N/A

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or Device Med-Systems. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researcher ("investigator") named above, or the research staff members who may assist him, any questions you have about this study at any time.

What is the purpose of this study?

You have been asked to be in the study because you are a woman over the age of 18 undergoing a certain type of abdominal surgery. It is possible that harmful adhesions may form in your abdomen after this surgery. Adhesions are similar to scar tissue and might prevent you from having children in the future.

This study is testing a product that might reduce or block these adhesions from forming. The product is called ADHESIABLOC® Gel. Although there are other methods to reduce or block adhesions, this study wants to find out whether ADHESIABLOC® Gel is as safe and effective as the other methods.

Are there any reasons you should not be in this study?

You should not be in this study if you:

1. are pregnant or lactating
2. are undergoing tubal sterilization ("getting your tubes tied"), reversal of sterilization, or certain other similar procedures (e.g. "tubal implantation") during the surgical procedure
3. are receiving cancer therapy including drugs and radiation within 3 weeks prior to your surgery
4. are suffering from coagulation disorders (related to either your blood or your lymph fluids), or are taking anticoagulants (medicines intended to prevent clotting)
5. have a history of hemochromatosis (a disease characterized by excessive absorption of iron in your diet)
6. have liver (hepatic) or kidney (renal) disorders
7. are diabetic and are taking oral or injected hypoglycemic medications
8. are suffering from any immune system deficiencies or disorders
9. are unsuitable for processing large fluid loads (e.g. patients with congestive heart failure)
10. have any absorbable instruments to stop bleeding (a hemostat) left in your abdomen
11. are receiving any other adhesion prevention agents, particularly those containing corticosteroids, NSAID's, or HYSKON® (Dextran)
12. will require medication or other liquids to be injected through your cervix into your uterus or fallopian tubes (post-surgical hydrotubation)
13. have an active pelvic or abdominal infection
14. will undergo peritoneal grafting (in which healthy tissue is taken from one part of your body to replace injured tissue in another part of your body) as part of your operative procedure
15. require any surgical procedure at the time of the initial surgical procedure (laparotomy) that involves opening the gastrointestinal or urinary tract
16. are found to have adhesions in 12 or more of the 24 anatomical sites examined as part of your initial operative procedure
17. will have one or more of the 24 anatomical sites removed during your initial operative procedure

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 50 people in this research study.

How long will your part in this study last?

The total study will be up to 20 weeks, from the first surgery to a second procedure that will look at your abdomen to determine whether any adhesions have formed (maximum not to exceed 24 weeks).

What will happen if you take part in the study?
This will be a double-blind study, which means that neither you nor the researcher will know if you are receiving ADHESIABLOC® Gel or an existing method of reducing or blocking adhesions. In case of an emergency, however, your course of treatment can be found through Device Med-System's records.

The following procedures will be performed on all subjects:

1. Initial Operative Procedures
Prior to your discharge from the hospital after your initial surgical procedure or within 4 days of the surgery, a series of tests (serum electrolytes, hematology and blood chemistries) will be performed. The investigator will record any adverse experiences that you note and/or those observed by the staff. By adverse experiences, we mean those that could include post-operative pain, nausea, infection, etc. The examination will also determine if there is too much fluid in your abdomen. In addition, you will be provided with a diary to document medications taken following discharge and to comment on your general status and health.

2. Check-Up Evaluations
Medical tests (serum electrolytes, hematology and blood chemistries) will again be performed at a check-up visit within 4 weeks after the initial procedure. The investigator will record any adverse experiences noted by you and/or observed by the staff. You will again be examined to determine if there is too much fluid in your abdomen. Your patient diary will be retrieved and a new one will be provided to you. Before you finish this visit, you will be interviewed regarding any ongoing or new adverse experiences.

3. Second-Look Operative Procedures
You will undergo a second-look procedure about 6 to 20 weeks following the first procedure (not to exceed 24 weeks). Prior to the surgery, some medical tests (serum electrolytes, hematology, blood chemistries, and urinalysis--including a urine pregnancy test) will again be performed. Your patient diary will be retrieved, and you will be interviewed regarding any ongoing or new adverse experiences. The second procedure will be videotaped. During the procedure, the investigator will perform an examination of your abdomen to determine whether you have any adhesions, excessive abdominal fluid, or other problems.

What are the possible benefits from being in this study?
This study will benefit society by allowing it to gain new knowledge on how to reduce or prevent adhesions. In addition, your participation in this study may reduce your risk of getting adhesions after your surgery.

What are the possible risks or discomforts involved with being in this study?
There are no known side effects or discomforts associated with ADHESIABLOC® Gel, but there may be uncommon or previously unknown risks. You should report any problems to the investigator or staff.

We do not know the effect of ADHESIABLOC® Gel on babies before they are born, or on nursing children. If you are planning to get pregnant, you should not be in the study. Pregnancy

tests will be done on all women who might be able to get pregnant at the start of the study. These tests will be paid for by Device Med-Systems. If you become pregnant during the study, you should notify the investigator **immediately.**

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive treatment. For other available treatments that may benefit you, please consult the investigator and staff.

What if we learn about new findings or information during the study?
During the course of this study, if we find or learn anything new that might make you want to stop participating, we will share this information with you.

How will your privacy be protected?
We will not identify you by name in any report or publication about this study. Although your privacy is essential to us and we try to keep our study records private, it is possible that a federal or state law may require us to disclosure personal information about the patients in our study. Although this is not likely, Device Med-Systems will try to protect the privacy of your personal information in this situation. It is also possible that research sponsors, government agencies, the FDA, and Device Med-Systems staff will need to see your personal information for safety reasons.

A copy of this consent form will go into your medical record. This will allow the doctors caring for you to know that you are participating in this study. This information will help them to take care of you in case you have any health problems.

What will happen if you are injured by this research?
All research involves a chance that something adverse might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or get an injury from being in this study. If such problems occur, the investigator and staff will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. Device Med-Systems has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. Upon your withdrawal you will no longer be enrolled in the trial and no further study procedures will be performed nor additional data will be collected. Any data collected prior to your withdrawal will continue to be used in connection with the study. If you choose to withdraw from this study you must notify the study doctor at the phone numbers listed on page 1 of this consent form for instructions on withdrawing from the study.

Can participation be terminated without the subject's consent?
The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not be compensated for taking part in this study.

Will it cost you anything to be in this study?
Although you will be billed for your routine medical care, it will not cost you anything extra to be in this study. The tests, visits or procedures that you will receive as part of this study will be the same as the care that you would normally have received for your surgery even if you had not participated in the study. You will be required to provide your own transportation to and from the study test site.

Who is sponsoring this study?
This research is funded and conducted by Device Med-Systems. The investigator and staff do not, however, have a direct financial interest in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or if a research-related injury occurs, you should contact the investigator listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact Coast Independent Review Board at (719) 325-8400, Monday - Friday, 8:00 a.m. - 5:00 p.m. Mountain Time. Collect calls will be accepted.

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent