Procedure Manual: Medical Abortion Using Mifeprex.

Purpose: To ensure that all patients coming into our clinic receive the safest procedure possible.

- After education is complete, make a copy of the signed Mifeprex Guide.
- The copy will be sent home with the patient.
- Collect medications for the patient.
- Get the desired birth control ready for the patient.
- Rhogam needs to be given.
- Get a glass of water for the patient to take Mifeprex.
- Notify the Physician that the patient is ready to be seen.
- The patient needs to stay in the clinic 30 minutes after taking the pill.
- The patient needs to schedule the 2 week follow-up before leaving the clinic.
- Patient should be logged in the Medical Follow-up book.
- If the patient does not return for the required 2 week follow-up, staff will need to contact them by phone. If staff is unsuccessful in reaching the patient 3 times, a letter will be mailed to the address given to the clinic by the patient.
- If the patient fails to reply, they will then be marked as "Non-Compliant" in the system and will not be allowed to choose the Medical procedure if returning to the clinic.
- Patients that return for the 2 week follow-up will be checked in and an ultrasound will be done to ensure the pregnancy tissue was evacuated from the uterus.

Procedure Manual: Identification of Products of Conception

Purpose: To ensure that the Products of Conception (POC) is complete for the gestation of the patients undergoing abortion before the patient leaves the clinic.

- After the abortion, the tissue will be rinsed and placed in a glass dish over the backlight.
- The Physician or a staff member trained to identify the POC will check all tissue for completeness. Results will be charted on the back of the patients chart in the appropriate area.
- Products of Conception under 10 weeks of gestation will have a photo taken. The picture number will be charted on the patient's chart.
- All tissue will then be placed in ziplock bag with Wavicide. This ziplock of tissue will be collected at the end of the day and placed in a red biohazard bag that will be put in the pickup container provided by the company assigned to dispose of our biohazard waste.
- POC's will be put in biohazard waste in the garage and Picked up by GRP.
- Any tissue that is questionable will be brought to the Physician's attention. The Physician will then determine if tissue and/or blood should be saved.

- Patients with questionable tissue will be instructed on ectopic precautions and may be given Methotrexate with the Physician's orders. Instructions and/or methotrexate given will be charted on the patients chart.
- If the POC was a result of rape, it will be put in sterile specimen cup, labeled and placed in the freezer for gestations under 12 weeks. 13 weeks and up place specimen in clean chuck.
- If a patient has opted to have the POC cremated, this may done at the patient's expense and needs to be approved before procedure begins.
- POC's that are frozen will be put in biohazard waste after 6 months.
- POC form will be filled out and put in patient chart.
- POC's will be clearly labeled with the patient's chart number. FI's can also be labeled with first initial and last name along with chart number.

Procedure Manual: Gestations under 6 weeks

Purpose: To ensure the procedure was successful.

- Any patient with a gestation below 6 weeks, must fill out Under Six Week consent form.
- These patients must agree to return to our clinic for follow-up. If the patient does not agree, they will not be seen.
- These patients will be logged as a Mandatory Follow-Up in the specimen book. If they do not return for a 4 week follow-up, we will attempt to be contacted by phone three times. If this is unsuccessful, a letter will be mailed to the address provided by the patient.

Procedure Manual: Possible Ectopic Pregnancy Protocol

Purpose: To ensure that all potential patients with an ectopic pregnancy are treated appropriately.

- Any patient with an empty uterus on ultrasound and a positive pregnancy test and any patient with a positive pregnancy test and ultrasound confirming a pregnancy that yields tissue unsatisfactory to confirm completion will be annotated in the "Mandatory Follow up Log" as a potential ectopic pregnancy. At the discretion of the physician the patient may be administered methotrexate at the dose of 50 mg / meter square or as directed.
- Each patient that falls into this category will be instructed, and their record annotated, that they must return in at least 48 hours but less than 14 days, or immediately for severe cramping or bleeding of greater than two pads per hour, for two hours.
- If an ectopic pregnancy is seen on ultrasound to accompany an intrauterine pregnancy (approx. 1/35,000 risk) the intrauterine pregnancy is to be terminated and the patient immediately transferred to the hospital of her choice.
- If the ectopic pregnancy does not have an intrauterine twin the patient is to be immediately referred for definitive treatment.

Attachment 2

AbortionClinics.Org 1002 West M. .on Ave, Bellevue, NE 68005 402-291-47ᵢ ax: 402-291-4643

Products of Conception

Patient Name_____ DOB_____

POC labeled_____ Date_____

Reason for keeping tissue_____

_____

_____

If POC is leaving the building, who is it being released to_____

Date Released_____ By_____

Signature of Recipient_____

If POC is returned to the building, place POC in biohazard waste bag and put in garage.

Date Returned_____ By_____

Signature of Staff that Received POC_____

Please attach any receipts and/or orders received.

Attachment
3

POC LOG

Date POC Put in Freezer	POC Labeled	Form in Chart	Remove By Date	Removed On	By

Procedure Manual: Environmental Safety

Purpose: To ensure the clinic is maintained in a manner that minimizes accidents.

- Keep surfaces smooth and free of sharp edges, mold, or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.
- Maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.
- Provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.
- Monitor and maintain water temperatures that accommodate comfort and preferences but not to exceed the following temperatures:
    - Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.

Procedure Manual: Hazardous/Poisonous Materials

Purpose: To ensure hazardous/poisonous materials are handled, stored and disposed of properly.

- All hazardous/poisonous materials will be kept in locked cabinets
- Gloves should be worn when handling these materials to prevent damage to skin
- hazardous/poisonous materials will be disposed of as suggested by MSDS
- Spill kits will be kept in close proximity of hazardous/poisonous materials
- Any biohazard materials will be put in red bags and put in biohazard trash in the garage

Procedure Manual: Management of Supplies

Purpose: To ensure the clinics supplies are stored, stocked and dated properly

One staff member will be assigned the task of ordering, organizing and keeping the supplies the clinic needs to operate.

This person will also be responsible for checking supplies for expiration dates and separating expired stock from good stock.

Expired stock will be disposed of properly.

Procedure Manual: Management of Laminaria Stock

Purpose: To ensure that laminaria are logged and not expired

When laminaria are received in the clinic, they should be logged with date received, type of laminaria, quantity, lot # and expiration date. All new stock should be put away in Room 1. The stock will be checked weekly when staff checks for expired instruments.

Procedure Manual: Instrument care

Purpose: To ensure that all instruments used in the facility are cleaned and/or sterilized properly.

- All instruments will be placed in a 10% bleach solution after use. The instruments will remain in solution for 10 minutes. Make sure all instruments are completely covered with the bleach solution before setting the timer.
- When the timer goes off the instruments will be taken out of the 10% bleach solution and placed in the sink.
- The sink will be filled with water and 1 oz of Alconox powder.
- All instruments will then be thoroughly scrubbed and rinsed.
- Instruments will then be placed on a towel to dry.
- After drying, the metal instruments will be placed in sterilization pouches and sealed with the sterilization tape.
- Using a permanent marker the name of the instrument, date, expiration date (6 months from current date), and the initials of the staff member will be written on the tape.
- All pouches will then be placed in the sterilizer.
- **Exceptions:** All speculums and 1st day tennaculums will be cleaned as above and without wrapping will placed directly in the autoclave.
- Sterilization will be at 270 degrees F for 20 min. at 27psi.
- Cannulas will be tossed and replaced with fresh, sterile cannulas after each use.

All suction tubing and bottles will be cleaned as above and then left to dry. These can be re-used immediately after cleaning. These do not need to be autoclaved.

Attachment
5

Laminaria Log

Date Received	Laminaria Brand	Size	Qty	Lot #	Expiration Date	Received By	Removed Date

Procedure Manual: Equipment Maintenance

Purpose: To ensure all of our equipment is maintained and logged according to the manufacture.

Ultrasounds:

Mindray Z-6 Maintenance
All functions of this device may be used. Maintenance should be as follows.

- Probes should be cleaned after every use
- Check the surface of the probe daily
- Clean display monthly
- Clean trackball monthly
- Clean control panel monthly
- Clean probe cable and the surface of connector monthly
- Clean all holders monthly
- Clean cover monthly
- Clean peripherals monthly
- Check power cable and plug monthly
- Check battery annually
- Check function of peripherals and options annually
- Mechanical safety inspection annually
- Electrical safety inspection every 2 years by authorized Mindray technician

The maintenance will be logged in the Machine Maintenance book located the in scrub room.

Shimadzu Ultrasound Maintenance
This machine is only used for simultaneous viewing during the procedure. This ultrasound will not be used to determine gestation.
The following maintenance will be performed monthly.

- External Cleaning
- Inspect power cord

EKG:

Burdick Medic 4 Maintenance
This device will ONLY be used as a cardiac monitor. The defibrillator capabilities will NEVER be used. The AED will be used in case of emergency.
Preventive Maintenance should be performed at least once per year. We will do these steps monthly.

- Visually inspect the defibrillator
- Clean the defibrillator
- Check the power cord
- Check the patient cable
- Inspect the printhead

The maintenance will be logged in the Machine Maintenance book located the in scrub room.

Electrocautery:

Birthcher 771-2 Maintenance
This device is used only for Vasectomy patients and setup is done by physician. Little maintenance is required for this machine. The following maintenance will be performed monthly.

- External Cleaning
- Inspect power cord

Oximeters:

Autocorr Maintenance
This device does not require any maintenance. The following maintenance will be performed monthly.

- Clean all external surfaces
- Inspect finger probe
- Inspect power cord

Burdick Oxy 100 Maintenance
This device does not require any maintenance. The following maintenance will be performed monthly.

- Clean all external surfaces
- Inspect finger probe
- Inspect power cord

Thermometers:

Welch Allyn SureTemp Plus Maintenance

- Check batteries
- Clean all external surfaces
- Remove/clean probe well

Mabis Maintenance

- Check batteries
- Clean all external surfaces

Hemoglobin

Hemopoint H2 Maintenance (see maintenance book)

- Disconnect power
- Housing and touch screen
- Microcuvette holder
- Optical unit
- Power adapter

Autoclaves

M11 UltraClave Steam Sterilizer Maintenance

The following maintenance procedures are to be performed.

Daily (patient days only):

- Clean external surfaces
- Clean Sterilizer Door Gasket

Weekly (patient weeks only):

- Drain reservoir
- Fill with new distilled water
- Clean chamber and Trays

Monthly Flush the System:

- Drain reservoir
- Fill with new distilled water
- Add 1 ounce of speed clean sterilizer to a cool chamber
- Run 30 minute cycle (packs) with no instruments
- Drain reservoir
- Fill with new distilled water
- Run 3 minute cycle (unwrapped)
- Drain reservoir and allow to cool to room temperature
- Remove trays and tray rack
- Wipe out the inside of the chamber, trays and rack
- Re-install the tray rack and trays
- Refill with new distilled water

Monthly Cleaning Chamber Filter:
- Before performing this procedure, make sure that the sterilizer has cooled to room temperature
- Remove all trays, tray rack, and tray plate from the chamber
- Locate the chamber filter on the bottom of the chamber
- Grasp filter and gently pull upwards while twisting slightly
- Clean the filter with mild soap and distilled water
- Rinse with distilled water
- Replace the filter

Monthly Maxi-Test

Monthly Pressure Relief Valve Check
- Remove the top inspection cover
- Select the unwrapped cycle and start the cycle
- When the "heat up" protion of the cycle is complete and the elapsed time is being counted down on the display panel, pull upward on wire ring of pressure relief valve with a screwdriver for approximately 3 seconds: steam should discharge freely from beneath the rear of the unit
- Release the wire ring
- Press stop to prevent the unit from overheating
- Install top inspection cover

Quarterly:
Remove and Clean Door Gasket:
- Remove dam gasket and door gasket from door
- Clean the gaskets with a mild detergent and inspect for cracks, cuts, shrinkage, or swelling.
- Clean gasket housing channel with mild soap and distilled water
- Press the door gasket into the channel then install dam gasket
- Run one cycle to seat the gaskets properly

Suction:

Synevac System 10 Maintenance:
The Synevac System is designed to make clean-up and maintenance quick and easy. There are no required maintenance checks for the vacuum pump and the unit requires no oil.

Daily Set-up (Patient Days Only):
- Attach tubing and bottles to the machine
- Use your finger to close off system.
- Turn on vacuum
- Document the maximum number displayed on vacuum gauge on daily flow log

Daily Cleaning (Patient Days Only):

- Prompt removal of spills will protect the cabinet finish. Use soap and water.
- Disconnect the tubing and remove the glass collection bottles. Soak tubing, rubber top and bottles in 10% bleach solution for 10 minutes and then wash with Alconox and water and allow to dry after each patient. The back bottle must be soaked at the end of the day unless contents from front bottle overflowed to the back bottle.
- Wipe down all surfaces of the machine with sani-wipe after each patient
- Replace rubber o rings and gaskets when they show signs of wear to insure consistent vacuum levels
- Check the disposable filter. If discolored, remove the filter and replace it with a new one
- Remove the overflow safety jar and ball float. Clean the parts with soap and water and let them dry

Monthly Visual Inspection

- Check all hoses for vacuum leaks.
- Check all hose connections into and out of the collection bottles and the disposable filter assembly.
- Check all gaskets and o rings. They must be fitted properly to insure a good seal.
- Check that the overflow jar is properly screwed into place.

Annual Functional Inspection

- Check the pump by removing the hose connected to the pump inlet fitting. Cover the fitting with your finger. Check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose.
- Remove the interconnecting hose from the disposable filter. Cover the metal female fitting on the interconnecting hose and check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose.
- Remove the interconnecting hose from the second bottle assembly. Cover the metal inlet port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the hose.
- Remove the collection set tubing to check the first collection bottle assembly and the interconnecting (bottle to bottle) hose. Cover the female metal port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the collection set.
- Cover the end of your collection set tubing. Check the gauge.

*If there is a leak in the system that you cannot locate, call for service.

Mindray Z-6 Maintenance

Date of purchased: 05/22/2014 Began Use: June 2014

2020

Clean the probes after every use. See Ultrasound policy
Daily Maintenance- Check surface of probe. See Ultrasound policy

Maintain Content	Frequency	Method	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean Display	Monthly	9.2.1												
Clean trackball	Monthly	9.2.1												
Clean control panel	Monthly	9.2.1												
Clean probes	Every use	9.2.1												
Clean probe cable and the surface of connctor	Monthly	9.2.1												
Clean all holders	Monthly	9.2.1												
Clean cover	Monthly	9.2.1												
Clean peripherals	Monthly	9.2.2												
Check surface of probe	Daily	9.3.1												
Check power cable and plug	Monthly	9.3.1												
Check battery	Annually	9.3.1												
Check function of Peripherals and options	Annually	9.3.3												
Mechanical safety inspection	Annually	9.3.4												
Electrical safety inspection	2 years	Service	Authorized Mindray Technician Only **Due June of even years											

Attachment 7

Maintenance Log Shimadzu 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Shimadzu 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Shimadzu 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Shimadzu 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Medic 4 (room 1) 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Medic 4 (room 1) 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Medic 4 (room 1) 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Medic 4 (room 1) 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Birtcher 771-2 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Birtcher 771-2 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Birtcher 771-2 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Birtcher 771-2 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Oximeter 2015

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2016

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2017

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2018

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2015

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Oximeter 2016

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Oximeter 2017

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Oximeter 2018

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Welch Allyn SureTemp Plus 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Welch Allyn SureTemp Plus 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Welch Allyn SureTemp Plus 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Welch Allyn SureTemp Plus 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Mabis Thermometer 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Mabis Thermometer 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Mabis Thermometer 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Mabis Thermometer 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Hemopoint H2 2015

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Maintenance Log Hemopoint H2 2016

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Maintenance Log Hemopoint H2 2017

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Maintenance Log Hemopoint H2 2018

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Monthly Visual Inspection

2016 **SV-10 #4568**

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check all hoses for vacuum leaks												
Check all hose connections into and out of the collection bottles and the disposable filter assembly												
Check all gaskets and o rings												
Check that the overflow jar is properly screwed into place												

Annual Functional Inspection

Check the pump by removing the hose connected to the pump inlet fitting. Cover the fitting with your finger Check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the disposable filter. Cover the metal female fitting on the interconnecting hose and check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the second bottle assembly. Cover the metal inlet port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the hose	
Remove the collection set tubing to check the first collection bottle assembly and the interconnecting (bottle to bottle) hose. Cover the female metal port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the collection set	
Cover the end of your collection set tubing. Check the gauge	

Monthly Visual Inspection

2016 **SV-10 #4226**

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check all hoses for vacuum leaks												
Check all hose connections into and out of the collection bottles and the disposable filter assembly												
Check all gaskets and o rings												
Check that the overflow jar is properly screwed into place												

Annual Functional Inspection

Check the pump by removing the hose connected to the pump inlet fitting. Cover the fitting with your finger Check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the disposable filter. Cover the metal female fitting on the interconnecting hose and check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the second bottle assembly. Cover the metal inlet port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the hose	
Remove the collection set tubing to check the first collection bottle assembly and the interconnecting (bottle to bottle) hose. Cover the female metal port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the collection set	
Cover the end of your collection set tubing. Check the gauge	

Daily Vacuum Flow Checks

2015 **SV-10 #4568**

	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
6												
7												
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Attachment 18

Daily Vacuum Flow Checks **2016** **SV-10 #4226**

	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
6												
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Attachment 19

Daily Autoclave Cleaning Log 2015 **V641964**

Day	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
6												
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Attachment 20

Daily Autoclave Cleaning Log

2015

ES-004740

Day	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
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Attachment 21

Weekly Log

2015 **V-641964**

Week	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												

Monthly Flush Log

January	February	March	April	May	June	July	August	September	October	November	December

Monthly Filter Log

January	February	March	April	May	June	July	August	September	October	November	December

Quarterly Log

January		April		July		October	

Maxi Test

January	February	March	April	May	June	July	August	September	October	November	December

****Please initial and date when completed. Thanks!****

Monthly Pressure Relief Log

***Supervisor to complete**

January	February	March	April	May	June	July	August	September	October	November	December

Attachment 22

Weekly Log

2015 **ES-004740**

Week	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												

Monthly Flush Log

January	February	March	April	May	June	July	August	September	October	November	December

Monthly Filter Log

January	February	March	April	May	June	July	August	September	October	November	December

Quarterly Log

January		April		July		October	

Maxi Test

January	February	March	April	May	June	July	August	September	October	November	December

****Please initial and date when completed. Thanks!****

Monthly Pressure Relief Log

***Supervisor to complete**

January	February	March	April	May	June	July	August	September	October	November	December

Attachment 23

LeRoy H Carhart, MD
1002 W. Mission Ave.
Bellevue, NE 68005

September 16, 2015

Nebraska DHHS Licensure Unit;

1. On August 13, 2015, I submitted my answers to Nebraska DHHS, to: "**Questions from DHHS Nebraska submitted on August 6, 2015, To Dr. LeRoy Carhart with responses.**"

2. A copy of the answers is attached.

3. When I was reviewing our responses on Nebraska DHHS Licensure Unit: Summary of Deficiencies," State Form 3UQ11, I realized that I had made a serious omission in my response to question 1. The answer as submitted is:

"... The sole exceptions to this policy occurs when we have:

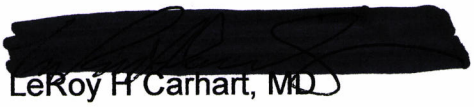
a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study.
b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence.
c) A request from the patient to have the tissue released to a licensed funeral director or his agent to prepare the fetus for cremation or burial.

4. The answer should have a new paragraph "c)" and paragraph "c)" needs to become paragraph "d)". The correct answer and the amendment needed to my response, changes underlined, should read:

"... The sole exceptions to this policy occurs when we have:

a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study.
b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence.
c) <u>A request from the patient, a legal guardian, a reporting authority or the attending physician to have the tissue saved so that should the authorities desire the specimen it will be available.</u>
d) A request from the patient to have the tissue released to a licensed funeral director or his agent to prepare the fetus for cremation or burial.

Respectfully submitted:



LeRoy H Carhart, MD

Attachment 1: Questions from DHHS Nebraska submitted on August 6, 2015, To Dr. LeRoy Carhart with responses, dated August 13, 2015.

LeRoy H Carhart, MD
1002 W. Mission Ave.
Bellevue, NE 68005

August 13, 2015

**Questions from DHHS Nebraska submitted on August 6, 2015,
To Dr. LeRoy Carhart with responses.**

2. What happens to the medical waste/fetal tissue after the procedure/abortion?

In accord with standard practices used in similar practice settings, in vacuum aspiration abortions, the tissue travels through a closed system into a collection jar containing a 10% bleach solution. At the end of the procedure the tissue and solution is filtered through a strainer to remove fetal tissue. Then the decontaminated tissue is then "floated" in tap water to identify the adequacy of fetal parts, to help determine that the abortion is complete. Following examination the tissue is put into a container containing "wavicide". At the end of the day or when the container is full, it is placed in a "hazardous waste" container to await pick-up from a certified medical waste disposal company. The sole exceptions to this policy occurs when we have:

a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study.
b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence.
c) A request from the patient to have the tissue released to a licensed funeral director or his agent to prepare the fetus for cremation or burial.

In accord with standard practices used in similar practice settings in each of these scenarios the tissue is prepared to meet the requirements of the agency concerned.

In accord with standard practices used in similar practice settings with second trimester (dilatation and evacuation) abortions the tissues are removed by forceps and vacuum aspiration. The vacuum aspirated portion is treated as above. The tissue removed by forceps is also submerged in the solution and floated for identification. It is also then placed in wavicide and placed in the "hazardous" waste container as described above.

3. Where is the medical waste tissue stored?

In accord with standard practices used in similar practice settings fetal tissue or products of conception are stored in red bagged "hazardous" waste containers in separate sealed pouches. The tissue is immersed in

wavicide. These containers are kept in our indoor garage area separated from the clinic by firewalls. The area is separately locked from the clinic.

4. How does the facility remove the medical waste?

MedPro Disposal is our agent to dispose of our medical waste. All containers and liners are supplied by the licensed carrier. A copy of our contract is attached as attachment 1. I have also attached as attachment 2, a copy of the receipt for our last pick up. As the "hazardous" waste containers become filled they are sealed. Once a month they are picked up by the licensed medical waste disposal company, MedPro Disposal. This is in accord with standard practices used in similar practice settings

5. Who all has access to the area where the medical waste is stored?

All staff members have access to the locked area. Current staff members are:

i. LeRoy H Carhart, M.D., Medical Director
ii. Mary Lou Carhart, Clinic Administrator
iii. Lindsey R Koch (Creekmore), R.N. Director of Nursing
iv. Melissa Hill, Medical Assistant
v. Ashley Edwards, Medical Assistant
vi. Shavon Meadows, Medical Assistant

6. Are individual fetal waste/specimens transported to any other facilities?

No fetal tissue has been transported to any other facility since we stopped donating tissue to the University of Nebraska. The last time occurred in the early 2000's.

7. Explain the role(s) of ultrasound used at the clinic i.e. prior to procedure and during the procedure?

Ultrasound's role is described in SOGC Guideline #303. A copy is furnished and incorporated into my answer as attachment 3. The role of the ultrasound at this facility is to aid in the determination of the gestational age of the fetus and to aid in the safety of the performance and the completion of the abortion.

8. What training do staff completing the ultrasound receive?

I have attached as Attachment #1. Our ultrasound training protocol.

9. How is their competency evaluated?

Every ultrasound is evaluated by me prior to the start of the abortion. I then use "real-time" ultrasound during the entire abortion procedure. I am

able to compare what the staff members sonogram shows with what I see in the operating room. All discrepancies and findings of note are reviewed on the spot with the technician that did the original sonogram. All measurements and placement are reviewed with the technician thus assuring that technician training and competency are evaluated daily.

10. Are pictures of the ultrasound printed off or is there a report printed off?

For 1st trimester abortions when only a single structure is measured only the picture with the measurements are printed. For 2nd trimester abortions or when multiple structures are measured, both the pictures and the reports are printed. The "Ultrasound Training Annual Review Form" is completed annually for each employee. The form is included as attachment 3.

11. How is gestational age determined?

A part of my answer to question ten appears in response to question 11 below. See that response. However, I am aware of the SOGC Clinical Practice Guidelines, and specifically Guideline # 303 published in February 2014 entitled "Determination of Gestational Age by Ultrasound". As is observed in the Abstract Summary Statement; "When performed with quality and precision, ultrasound alone is more accurate than a "certain" menstrual date for determining gestational age in the 1st and 2nd trimesters in spontaneous conceptions, and it is the best method for estimating the delivery date." I attempt to adhere to the SOGC Guideline.

12. What are the guidelines for weeks of gestation? (Particularly 20 weeks and over) i.e. which procedure is used?

A part of my answer to question eleven appears in response to question 10 above. See that response.

It is common in most obstetrical circles in the United States to define gestation age using the pregnancy start date as the first day of the mother's last normal menstrual cycle (LNMP). Thus when a woman misses her first menstrual cycle she is said to be four weeks pregnant.

The State of Nebraska has chosen to use the actual date of conception as the first day of the pregnancy. Thus on the day of the first missed menstrual cycle the woman is said to have a gestation age of two weeks.

Establishing a patient's gestation is best done using clinical judgement. This should take into account all available parameters to include history, physical exam, ultrasound and other test results that may add to the thought process.

13. Have you been approached in regards to the purchase of fetal tissue?

I have never been approached to sell tissue at any of my practice locations.

From time to time groups that collect tissue for scientific reasons have attended medical meetings and continuing education programs that I have also attended. I do not know whether it is accurate to say that I have been approached, but I have told at least one of these groups at some time past not expressly recalled that my protocols and the state law, as I understand it, preclude my donation of fetal tissue.

As I am well aware of both the law and ethics involved I have never even considered a sale of said tissues.

Respectfully submitted:

LeRoy H Carhart, MD

Attachment 1: Contract with MedPro Disposal
2: Last Invoice from MedPro Disposal with receipt
3: SOGC Guideline #303 "Determination of Gestational Age by Ultrasound"
4: Ultrasound Policy
5: Ultrasound Training Form
6: Ultrasound Training Annual Review Form