CANADA FILLER MART, INC DBA DERMAL DISTRIBUTORS OUTLET

Policies and Operating Procedures

MARCH 1, 2023

CANADA FILLER MART, INC

Edmonton, Alberta, Canada

Canada Filler Mart, INC
operating as
Dermal Distributors Outlet

Trustee Statement of Accountability

Dermal Distributors Outlet is granted a Medical Device Establishment Licence (MDEL) no. 23703 by Health Canada. This Licence entitles the company to import and distribute Class 3 medical devices in Canada.

Dermal Distributors Outlet resources includes two owners/directors and one support staff. All stakeholders have been formally consulted and briefed on the policies and procedures in this document.

These written policies and procedures provide direction to each person at Dermal Distributors Outlet on how personal and business information is to be protected as it is collected, accessed, used and disclosed. Third parties who collect, access use, or disclose personal or business information on behalf of Dermal Distributors Outlet must also adhere to these policies and procedures. Information Management Service Providers and delivery agencies must meet or exceed the standards of these policies.

All accesses, uses and disclosures of personal or business information is restricted to those who are authorized by one of the directors at and Dermal Distributors Outlet to have access privileges and have a need-to-know the information to carry out their duties.

Corey Ralph (Owner, Director) is named co-CEO and is responsible for all policies and procedures, education and training. Mr. Ralph is also COO of marketing, client relations and sales. Dr. Lloyd Tapper (Owner, Director) is named co-CEO and is responsible for business decisions and is Medical Director ensuring all products adhere to Health Canada's approved list of Class III devices. Rebecca Gibson is the office manager and the frontline, client relationship services personnel. Ms. Gibson, is the first point of contact for clients regarding products and services.

The undersigned Trustees have read understood and fully support the policies and procedures in this Policy Manual dated April 15th, 2023. Each stakeholder has reviewed the Management Agreement, the business Exit Agreement and an Acceptable Use Agreement.

Signature(s) of Directors(s)

Lloyd Tapper

Co-CEO and Medical Director
Dermal Distributors Outlet

Rebecca Gibson — April 15, 2023

Witness — Date

Corey Ralph

Corey Ralph
Co-CEO and Director of Privacy & Security Officer
COO Marketing, Client Relations, Sales
Dermal Distributors Outlet

Rebecca Gibson — April 15, 2023

Witness — Date

Introduction

Canada Filler Mart, INC operating as Dermal Distributors Outlet is a Health Canada MDEL (no. 23703) certified national Canadian company operating from its location in Edmonton, Alberta Canada.

The business includes Lloyd Tapper, a PhD prepared family nurse practitioner, who performs quality assurance and adherence for all Cass III medical devices approved Health Canada and permitted to be imported/distributed by Dermal Distributors Outlet.

Corey Ralph holds a master's in business administration and has spent the last 15 years working in the Information Technology sector. He is the security and privacy director for Dermal Distributors Outlet and is responsible for ongoing monitoring of the use, storage and disclosure of client or business information. He is also responsible for the ongoing education and training of Dermal Distributors Outlet staff regarding privacy, security and information management.

Dermal Distributors Outlet has established arrangements and sales agreements with professionals, businesses and establishments that perform injectable cosmetics services. These agreements allow these specialized establishments to purchase Class III, Health Canada approved medical devices.

Privacy and Security Statement

Lloyd Tapper and Corey Ralph are co-owners of Canada Filler Mart, INC operating as Dermal Distributors Outlet. Corey Ralph is Office Manager, Privacy Officer and Security Director who has been appointed Assistant Privacy Officer. He will manage the day-to-day compliance with these policies and procedures and will be the point of contact for clients and employees and others for privacy-related questions and issues. All employees and staff are made aware of the roles of the Privacy Officer and the Office Manager through conversations, posters and other materials.

Dermal Distributors Outlet shall maintain policies and procedures to promote knowledge and awareness of the rights of clients including the right to access their own personal and business information and to request amendment of it where there are errors and omissions. Policies and procedures will also be established to maintain administrative, technical and physical safeguards to protect personal and business information. These policies and procedures are reviewed annually and amended as required.

All employees and staff, at Dermal Distributors Outlet are obligated to protect personal and business information in accordance with Health Canada and this Policy Manual, which includes the signing of a confidentiality agreement annually.

Dermal Distributors Outlet creates a culture of privacy by awareness activities, educational opportunities and privacy and security training to ensure compliance.

Dermal Distributors Outlet takes reasonable steps to ensure the personal and business information collected, used and disclosed is accurate and complete and its integrity is preserved.
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Dermal Distributors Outlet provides clients with information on the purpose for the collection, use and disclosure of their personal and business information and is open with clients about the business's privacy and information practices. Requests may be made verbally or in writing.

Dermal Distributors Outlet provides a confidential process for clients to lodge a complaint regarding the business's adherence to it policies and procedures, or to notify the business of a potential or suspected breach of privacy.

Dermal Distributors Outlet provides clients with access to their own personal and business information upon request. Requests may be made in writing.

Dermal Distributors Outlet responds to all requests from clients to amend their personal and business information. Factual personal and business information that is incorrect will be corrected when reasonably possible.

Dermal Distributors Outlet recognizes the right of a client to designate someone to make decisions on their behalf regarding the collection, use and disclosure of their personal and business information. Others may make decisions about a client's personal and business information when authorized to do so by law.

Dermal Distributors Outlet collects only the personal and business information that is reasonably necessary to provide sales and services.

Dermal Distributors Outlet discloses personal and business information as part of providing sales/services to its clients. If personal and business information is disclosed for other purposes, it will be with the consent of the client, or the disclosure is authorized without consent by law.

Dermal Distributors Outlet will take all reasonable steps to comply with a client's request to limit the collection, use and disclosure of their personal and business information.

Dermal Distributors Outlet uses written agreements to establish responsibilities and mitigate risk when third parties are using personal and business information on behalf of the practice or to whom and Dermal Distributors Outlet has disclosed personal and business information.

Dermal Distributors Outlet considers a privacy breach as a collection, use or disclosure of personal and business information in contravention of *Privacy Act* and these policies.

Dermal Distributors Outlet responds promptly to potential, suspected and confirmed privacy and security breaches. The Privacy Officer will engage the necessary expertise in managing breaches.

Dermal Distributors Outlet maintains up-to-date business continuity and disaster recovery plans that provide guidance on how to manage an interruption in business due to unplanned events.

Dermal Distributors Outlet maintains security software licenses that provide regular updates to the firewall, anti-virus, malware and the virtual private network software. And these automated updates are validated at the beginning of each quarter.

Dermal Distributors Outlet ensures that the operating manager's physical office space is secure.

1. Duties of the Privacy Officer, Privacy and Security Director and Office Manager	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy

Lloyd Tapper, NP is the Compliance and Quality Assurance Director for Canada Filler Mart, INC. operating as Dermal Distributors Outlet. Corey Ralph is Operations, Privacy Officer and Security, and Marketing and Sales Director who has been appointed Assistant Privacy Officer by the owners of Dermal Distributors Outlet. He will manage the day-to-day compliance with these policies and procedures and will be the point of contact for clients and employees and others for privacy- related questions and issues. All employees and staff are made aware of the roles of the Privacy Officer and the Office Manager through conversations, posters and other materials.

Dermal Distributors Outlet shall maintain policies and procedures to promote knowledge and awareness of the rights of clients including the right to access their own personal and business information and to request amendment of it where there are errors and omissions. Policies and procedures will also be established to maintain administrative, technical and physical safeguards to protect personal and business information. These policies and procedures are reviewed annually and amended as required.

Procedures

1. Quarterly the Privacy Officer and Privacy and Security Director will review audits to ensure no breeches of information have occurred.

2. The Privacy and Security Director will ensure all new hires, contactors; third-parties have the appropriate documents and agreements signed.

3. The Privacy and Security Director will ensure that all new staff receives an electronic copy of these policies and procedures documents.

4. The Privacy and Security Director will provide semi annual refresher training to staff and contractors.

2. Obligations of Health Professional and Employees	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Confidentiality Agreement	

Policy Statement
All employees and staff at Dermal Distributors Outlet are obligated to protect personal and business information in accordance with HIA and HPA, and this Policy Manual, which includes the signing of a confidentiality agreement annually.

Procedures

1. All employees and staff at Dermal Distributors Outlet
   1.1. Receive an electronic copy of this Policy Manual to read and use.

   1.2. Ensure they understand all policies and procedures and ask for clarification when they do not understand.

   1.3. Participate in all education and training offered by Dermal Distributors Outlet.

   1.4. Are responsible and accountable for ensuring the protection and security of personal and business information they collect, use, and disclose and assist others to do the same.

   1.5. Are responsible and accountable for assisting clients in any request for their personal and business information, requests for amendments to their personal and business information, and inquires on the privacy practices of Dermal Distributors Outlet.

   1.6. Sign an agreement that will be held in each employee's personnel file or with correspondence related to the person's engagement. It is a condition of engagement with Dermal Distributors Outlet that all professionals and third parties sign a confidentiality agreement.

   1.7. The signed agreement will be held in each employee's personnel file or with correspondence related to the person's engagement.

2. Those who do not comply with these procedures will be considered in breach of the Privacy Act and the policies and procedures of Dermal Distributors Outlet will be subject to disciplinary action by Dermal Distributors Outlet, the Privacy Act regulatory authority, or the courts.

3. Privacy and Security Awareness, Education and Training	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Confidentiality Agreement	

Policy Statement
Dermal Distributors Outlet creates a culture of privacy by awareness activities, educational opportunities and privacy and security training to ensure compliance with the Alberta Privacy Act by employees and staff.

Procedures
1. The Privacy and Security Statements will be posted in a place visible to all employees and staff working at the practice.

2. The Office Manager and/or the Privacy and Security Director are responsible for developing and maintaining an educational program about these policies and procedures.

3. Training is provided to professionals, employees and third parties who require training on privacy and security procedures such as faxing, emailing, scanning, storage, backups, destruction and other activities as identified.

4. The Office Manager provides orientation to new employees and staff on their first day. This orientation includes a thorough discussion of the privacy and security policies and procedures.
    4.1. New employees and staff are given a copy of the Policy Manual.

    4.2. New employees and staff sign the confidentiality agreement before they are provided with access to personal and business information.

    4.3. New professionals, employees and IT support personnel sign an acceptable use agreement before they are given a username and password for the EMR where applicable.

4. Accuracy and Integrity	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
Dermal Distributors Outlet takes reasonable steps to ensure the personal and business information collected, used and disclosed is accurate and complete and its integrity is preserved.

Procedures
1. Records are updated during the sale or interaction as soon as possible afterwards.
   The client's record includes:
   1.1. The date or purchase or engagement.

   1.2. The products purchased.

   1.3. The payment method (credit card, e-transfer).

   1.4. Billing and shipping addresses.

2. The records are to be kept in a systematic manner.

3. Dermal Distributors Outlet takes steps to improve the accuracy of the information collected, which includes:
   3.1. That it be written in clear language with only common abbreviations used.

   3.2. The record has the date, time, and the name of the author.

   3.3. Additions and corrections are made in a manner that allows the original information to still be read.

   3.4. Scanned documents and photocopies are complete and readable.

   3.5. Staff resources are trained on how to keep accurate records.

4. Dermal Distributors Outlet takes steps to protect the integrity of the personal and business information which include:
   4.1. Accurate recording of the personal and business information.
      4.1.1. Updating records when notified of corrections.

      4.1.2. Notifying other trustees when an amendment or notation is made in the record.

   4.2. Accurate scanning and photocopying of personal and business information.

4.3. Perform daily backups and periodically confirm the reliability of the backups.
4.4. Ensure secure and environmentally safe storage.

4.5. Audit access to personal and business information.

4.6. Use up-to-date security software.

4.7. Limit access to those who need to know the information.

5. Identified Purpose and Openness	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Poster	

Policy Statement

Dermal Distributors Outlet provides clients with information on the purposes for the collection, use or disclosure of their personal and business information and is open with clients about its privacy and information practices.

Procedures

1. The Office Manager ensures that information is posted about Dermal Distributors Outlet' privacy practices at reception and on its social media and website.
2. The poster will contain at a minimum:
   2.1. The name and contact information for the Privacy Officer or the Privacy and Security Director or the Office Manager.

   2.2. Information about Dermal Distributors Outlet' information handling practices.

   2.3. Information about how a client can manage consent through masking or an alternative method.

   2.4. The anticipated uses and disclosures of personal and business information.

   2.5. How clients can ask for access to their personal and business information and how to request an amendment to errors and omissions.

   2.6. How clients can make a complaint to the Office of the Information and Privacy Commissioner of Alberta.

3. Staff and employees, and anyone authorized to collect personal and business information will answer all questions about the anticipated collection, uses and disclosures of the personal and business information.

6. Challenging Compliance	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Confidentiality Agreement	

Policy Statement:

Dermal Distributors Outlet provides a confidential process for clients to lodge a complaint regarding the business' adherence to it policies and procedures, or to notify the business of a potential or suspected breach of privacy.

Procedures:

1. A client may submit a complaint to any employee in writing or verbally.

2. The Office Manager will be notified of the complaint as soon as possible, or at least before the end of the business office hours.

3. The Office Manager is responsible for responding to the complaint.
    a. If the complaint is a suspected privacy or security breach the Office Manager will activate the breach management plan.

    b. All discussions and actions related to the complaint will be documented.

4. The response to the client may be provided verbally.

5. A periodic analysis is made of all complaints to determine if there are systemic issues that must be addressed through updates in policies, changes in education, awareness, training or other action.

6. A client making a complaint or dissatisfied with the response will be provided with information on how to contact the Office of the Information and Privacy Commissioner of Alberta.

1. Amending Client Record upon Request	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Request for Amendment Form, Letter confirming amendment, Letter notifying of Notation, Letter regarding amendment or notation to another trustee	

Policy Statement

Dermal Distributors Outlet responds to all requests from clients to amend their personal and business information. Factual personal and business information that is incorrect will be corrected when reasonably possible. Opinions of the professionals at Dermal Distributors Outlet and other trustees will be amended at the business's discretion. If an amendment is not made a notation must be added to the record.

Procedures

1. All requests must be in writing.

2. The Office Manager will assist the client in completing the application form.

3. Amendments are made to factual information.

Receiving the Request

4. All applications from a client for amendment are dated and signed by the Office Manager the day the completed application is received by the practice.
   - 4.1. Amendments or notations are made as soon as possible and, in any event, not more than 30 calendar days after receiving the completed request.
   - 4.2. The Office Manager must be satisfied of the identity of the person making the application. For most clients this will have occurred at the time the client requested the change.
   - 4.3. Amendments are made by recording the correct information in the record and striking out the incorrect information in a manner that still allows the incorrect information to be read.
   - 4.4. When it is not possible to record the amended information in the record a note will be added to the record that directs anyone accessing the record to the location of the amended information.

8. Collection	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement

Dermal Distributors Outlet collects only the personal and business information that is reasonably necessary to provide an engagement or sale to a client.

Procedures

1. Anyone collecting, using, and disclosing the personal and business information based on implied consent must be able to form the opinion that the client will also consent to the use or disclosure if asked.

2. The client is believed to have provided consent to the collection if there is a poster advising of the purposes of the collection at the registration desk and the client gives the information.

3. The business collects the personal and business information directly from the client unless the client consents to collection from another source or the collection is authorized by law.

4. A client may revoke his or her consent for the collection of personal and business information and the business will take reasonable steps to comply with the revocation promptly.

5. Personal and business information will be collected indirectly when:

   5.1. The client consents to collection from another source.
   5.2. The client is unable to provide the information.
   5.3. The information is available to the public.

6. Dermal Distributors Outlet takes reasonable steps to ensure that the information collected is accurate and complete.

7. Only the minimum amount of information required is collected. This includes:
   - Company name
   - Contact person(s)
   - Mailing and Billing address
   - Phone/fax/email

9. Use of Personal or Business Information	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement

Dermal Distributors Outlet uses the minimal amount of personal and business information necessary to conduct business with its clients.

Procedures

1. Dermal Distributors Outlet uses personal and business information, based on implied consent for:
    a. Sales
    b. Promotional materials
    c. Informing of product changes, recalls, etc.

2. The business uses the least amount of personal and business information necessary for the purpose.
3. All uses are consistent with the ethical practices of the business.
4. A client may revoke his or her consent for the use of personal and business information and the business will take reasonable steps to comply with the revocation promptly.
    a. A revocation is not retroactive.

5. Authorization to use personal and business information is restricted to those who need it to meet the requirements of their role.
    a. All professionals, staff and employees, have access restricted through job description, letters of engagement, and through technical features available in the client relationship management (CRM) where applicable, including role-based access controls and masking.

6. Personal and business information collected from clients is used by Dermal Distributors Outlet for Provision Sales and Marketing:
    - Company name
    - Contact person(s)
    - Mailing and Billing address
    - Phone/fax/email

10. Disclosure	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement

Dermal Distributors Outlet discloses personal and business information as part of providing services to its clients. If personal and business information is disclosed for other purposes, it will be with the consent of the client or the disclosure is authorized without consent by law.

Procedures

1. Whenever possible, disclosures are noted in the client CRM.

2. Dermal Distributors Outlet will make reasonable efforts to inform clients of any disclosure of their personal and business information upon request.

3. A client may revoke his or her consent for the disclosure of personal and business information and the business will take reasonable steps to comply with the revocation promptly.

4. Dermal Distributors Outlet discloses personal and business information to non-trustees, who are professional, in accordance with the ethical practices of that trustee's profession.

5. Dermal Distributors Outlet discloses personal and business information when complying with a subpoena or warrant issued by a court, person or body that has the authority to compel the production of the information.

6. Dermal Distributors Outlet discloses personal and business information to the police when an authorized request has been made related to enforcing *The Criminal Code* or *The Controlled Drugs and Substance Act* or carrying out a lawful investigation under of those Acts and the information is limited to what is authorized in the Acts.

11. Agreements	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Confidentiality Agreement	

Policy

Dermal Distributors Outlet uses written agreements to establish responsibilities and mitigate risk when third parties inadvertently see personal and business information.

Procedures
Information Management Service Providers (IMSP) Agreements

1. Agreements with IMSPs cover:
    - Name of the parties
    - Authority to enter into the agreement
    - Duration of agreement
    - Description of services to be provided
    - Description of personal and business information that is the subject of the agreement
    - Responsibilities of both parties
    - Privacy and security requirements
    - Price/Fees
    - Terms
    - Indemnification
    - Termination

2. Dermal Distributors Outlet currently uses IMSP agreements with companies and individuals that process, store, archive or destroy personal and business information on behalf of Dermal Distributors Outlet or provide information technology services. This includes:
    - Iron Mountain

Other Agreements with Third Parties

3. Dermal Distributors Outlet also has agreements with other companies and individuals who may inadvertently see personal and business information. This includes:
    - Security company
    - Cleaning company

4. Contracts and agreements are used by Dermal Distributors Outlet when the disclosure of personal and business information is ongoing, such as when a third party provides a service on behalf of the business.

Internal agreements

5. Partnership Agreement: Dermal Distributors Outlet has partnership agreements that are signed by all business owners/representatives.

12. Management of Breaches	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Privacy and Security Breach Reporting Form, Breach notification letter	

Policy Statement

Dermal Distributors Outlet considers a privacy breach as a collection, use or disclosure of personal and business information in contravention of these policies. Dermal Distributors Outlet responds promptly to potential, suspected and confirmed privacy and security breaches. The Privacy Officer will engage the necessary expertise in managing breaches.

Definitions

Types of Breaches, a breach may be any or all of these:
Confidentiality: personal and business information becomes known or is at risk of becoming known by a person who does not have a need to know the information and is not authorized to see the information.

Integrity: personal and business information has been modified or in some other way has been interfered with such that Dermal Distributors Outlet or a client does not consider the information reliable.

Availability: personal and business information has been stolen, lost, moved, destroyed, blocked from view or in some manner is not available to and Dermal Distributors Outlet or the client.

Procedures

1. The first person aware of the suspected breach will take actions to stop or contain the breach if it is ongoing.
   1.1. Anyone aware of a suspected breach shall notify the Office Manager or Privacy Officer immediately.

2. The Office Manager works with the staff and employees to ensure
   2.1. Unauthorized copies of the personal and business information are retrieved from anyone not authorized to have the information, or notification of the destruction of the information is received. The notification of destruction includes the type of information that was involved in the suspected breach.

   2.2. Disconnection of the information systems, from the Internet and the Network if they have been compromised.

   2.3. Deactivate the user account if an authorized user is accessing personal and business information inappropriately.

Investigation and Analysis

6. The Privacy Officer leads an internal investigation into the suspected breach which includes:
   6.1. Establishing an investigation team with the necessary expertise which may include the other staff or employees at and Dermal Distributors Outlet, experts from other businesses, and other trustees who may have their own accountability for the information.

   6.2. Understanding the circumstances of the breach and determining if it was a breach of personal and business information.

   6.3. Examining physical and technical security and business process for a role in the breach.

   6.4. Identifying anyone who may have had unauthorized access to the personal and business information through the examination of audit logs of the CRM.

   6.5. The Office Manager thoroughly documents the breach.

   6.6. Determine if an actual breach occurred.

   6.7. Document recommendations and develop strategies to minimize future risks at the medical practice.

Notification of Others

7. The Office manager contacts key stakeholders as appropriate for the breach.
   7.1. The Information and Privacy Commissioner may be contacted for assistance and advice on managing the breach or notification of clients.
   - Telephone: 780-427-8089
   - Toll Free in Alberta: 1-888-878-4044

   7.2. The Information and Privacy Commissioner should be contacted if the breach will cause significant harm to the clients whose information was breached, involves many clients, or is systemic in nature and the Commissioner may want to notify other trustees of the potential for a similar breach.

   7.3. The Office of the Information and Privacy Commissioner of Alberta may be contacted for assistance and advice on managing the breach or notification of clients.
   - Telephone: 780-427-8089
   - Toll Free in Alberta: 1-888-878-4044

   7.4. Contact the police if there is possible criminal activity.

7.5. Contact legal counsel and insurers if deemed appropriate.

Notification of Clients

8. The Office Manager assists the directors in notifying all clients whose privacy has been breached.
   8.1. Clients are notified as soon as possible, considering when the breach and the potential harm to the client are understood.
   8.2. Notification of clients is made by telephone, mail or email.
   8.3. A notification to a client about a breach includes
   - the date of breach
   - details of the extent of the breach and the personal and business information involved
   - the steps that have been taken to address the breach both in the immediate and long term
   - the potential risks to the client
   - how the client can contact the Information and Privacy Commissioner of Alberta

9. The Privacy Officer may contact the Information and Privacy Commissioner of Alberta to assist in determining the most appropriate method of notifying clients.
   9.1. The Office of the Information and Privacy Commissioner of Alberta may recommend indirect notification of clients through the news media, a website or a poster in the business when direct notification is not possible or inappropriate in the situation.

Prevention

10. Implement recommendations and strategies to minimize future risks at the business.
11. The Office Manager ensures that the containment and notification recommendations of this policy have been met.
12. Lloyd Tapper, NP and Corey Ralph, MBA ensures the progressive discipline policy of Dermal Distributors Outlet is followed if an employee is involved
13. If the breach occurred at the Information Management Agreement (IMA), or with a third party the contract will be reviewed.
14. The Office Manager reviews these policies and procedures after the completion of the investigation and makes any necessary changes based on the lessons learned.
15. The Office Manager arranges for additional training on lessons learned to staff, employees, other professionals and third parties.
16. Dermal Distributors Outlet cooperates with any and all investigations by the

Information and Privacy Commissioner of Alberta into a breach of privacy at the business.

Penalties

17. When a privacy breach has been substantiated, the Privacy Officer determines if it was willful or unintentional
    17.1. Users who unintentionally collect, use, access or disclose personal and business information without authorization are subject to all or any of the following:
        - further privacy training
        - suspension without pay for one day
        - dismissal

    17.2. Users who willfully collect, use, access or disclose personal and business information without authorization are subject to all or any of the following
        - further privacy training
        - suspension without pay for up to five days
        - dismissal

13. Business Continuity and Disaster Recovery Plan	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement

Dermal Distributors Outlet maintains up-to-date business continuity and disaster recovery plans that provide guidance on how to manage an interruption in business due to unplanned events.

Procedures

1. The business continuity plan includes:
   1.1. Names, contact information and roles for Dermal Distributors Outlet' crisis management team.

   1.2. Emergency contact numbers.

   1.3. Staff and employees and third parties contact numbers.

2. The disaster recovery plan includes:
   2.1. A list of all IT and telecommunications systems with contact information for assistance.

   2.2. A checklist of actions that should be taken in an emergency to protect systems.

   2.3. A step-by-step process for resuming the normal operations of the technical solutions.

   2.4. The location of backups and how to access them if necessary.
      2.4.1. At least one person is trained in recovering a backup and is responsible to conduct semi-annual testing of the backup.

3. The business continuity and disaster recovery plan will be reviewed annually and updated as necessary.

14. Backups and Storage	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement:

Lloyd Tapper, NP and Corey Ralph, MBA maintains a program to backup all electronic administrative records and to store the backups securely.

Procedures

1. The Office Manager carries out the duties related to backups.

Onsite Backups

2. The schedule for automatic encrypted backups.
   2.1. Backup devices are reused on rotation schedule which provides data recovery access for up to 13 months, which is adequate from a disaster recovery/availability:
      - daily incremental backups – use a 7 day rotation of backup devices
      - weekly complete backups – use a 5 week rotation of backup devices
      - annual complete backup –stored securely in an offsite safe and kept for two years
3. The Office Manager will at least quarterly test the reliability of the backed-up information
   3.1. Testing the backups will be done by a qualified IT specialist and using a second server.

Recovering Information from Backup Devices

4. If the information on the technical solution becomes corrupt, the hard drive crashes or the server is stolen; Fijitsu is contacted to recover the information on the backup and to transfer it to an operating server.

Administrative Records

5. Electronic administrative records that are inactive for five years are copied onto an encrypted hard drive storage device by the Office Manager.
   5.1. Each year when new files are added the Office Manager confirms that previously stored records are accessible and readable.

   5.2. Administrative records that remain inactive for an additional two years are deleted from the storage device

15. User Account Management	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Acceptable Use Agreement	

Policy Statement

Each person with access to the office computers will have their own user name and password. Background checks to be performed prior to employment. Local Police background check to be completed.

Procedures

1. The Office Manager manages the creation and deletion of user accounts and has the administrative rights to change the privileges for each user.

2. Before each user is assigned access to the information system, they are required to sign an Acceptable Use Agreement.

3. The user name and password are the equivalent of a signature for ensuring users only access the personal and business information they need to know to perform their role at Dermal Distributors Outlet.

4. Each user will be authorized to view, use and print the personal and business information according to the requirements of that person's position.

5. A user's account is suspended should any concerns arise about the use of the account. If the issue is resolved, the account will be re-activated.

6. Each new employee is required to have a background check completed prior to commencement of employment. A copy of the background check will be stored with the employee's HR file.

Passwords

7. Users select their own passwords, which are a minimum of eight characters and are a combination of numbers, letters, symbols, and upper and lower case.

8. Passwords are changed every three months.

9. Passwords must never be shared with anyone else.

Penalties

10. Accessing information systems without appropriate authorization is seen as a privacy breach.
11. When accesses are deemed inappropriate, or a privacy breach has been substantiated the Privacy Officer determines if it was willful or unintentional.

a. Users who unintentionally access personal and business information are subject to all or any of the following:
   - further privacy training
   - loss of privileges to use systems
   - suspension without pay for one day
   - dismissal

b. Users who willfully access personal and business information are subject to all or any of the following:
   - further privacy training
   - loss of privileges to use systems
   - suspension without pay for one day
   - dismissal

16. Destruction of Office Equipment and Medical Devices and Retaining Personal and Business Information

Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
Dermal Distributors Outlet ensures that all personal and business information is removed from office equipment and medical devices before the devices are disposed.

Procedures

1. Neither the office equipment nor medical devices will be disposed of in the regular garbage or recycling.

2. The Office Manager maintains a list of office equipment and medical devices that could possibly retain personal and business information. The list of such devices as of April 2023 is:

    - 1 laptop computers
    - 1 desktop computers
    - 1 fax machines
    - 1 photocopier
    - 1 USB memory keys
    - 1 External Hard Drive
    - 1 cell phones
    - 1 scanner

3. A record of destruction is kept by the Office Manager with the date, who destroyed the equipment, how and why it was destroyed. The record includes:
    - Description of equipment destroyed
    - Date the equipment was destroyed
    - How the equipment was destroyed
    - Why the equipment was destroyed
    - Who destroyed the equipment

4. Any device retaining the primary source of the personal and business information is examined by the Office Manager to ensure the information has been properly archived or transferred to the replacement device. The old device is not destroyed until the Office Manager has confirmed the accuracy and integrity of the transferred information.
    a. This procedure applies to the client server, laptops and desktop computers, photocopiers and scanners.

17. General Security Software	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement

Dermal Distributors Outlet maintains security software licenses that provide regular updates to the firewall, anti-virus, encryption, malware and the virtual private network software.

Procedures

1. The Office Manager maintains a license for security services, which includes firewall protection, encryption for emails, and scanning emails for viruses.

2. All servers, computers, USB keys and mobile devices purchased by the business will include encryption capabilities.

3. The Office Manager maintains other security software update licenses as appropriate.

4. The Office Manager reviews the security updates from the vendor quarterly to ensure updates have been received and installed.

5. Audit logs are reviewed monthly to ensure access to Health information has not been breached. This activity is performed by the Privacy Officer and the Office Manager.

18. Security of the Office	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
Dermal Distributors Outlet ensures that the practice's physical office space is secure.

Procedures

1. Dermal Distributors Outlet is a home-based practice and owner of the premises.
    a. The property owner has provided an alarm system for the office.

2. The Office Manager manages the office keys and the opening and closing of the office each day.

3. Monitors, printers, and fax machines are placed where clients, unauthorized staff and others cannot see the personal and business information on them.

4. Portable equipment such as laptops, external hard drives, USB keys, CDs are stored in a secure location.

5. Portable equipment is never to be left unattended when taken outside the office, such as in cars or homes.

6. All portable equipment has strong encryption and all personal and business information on portable equipment is encrypted.

7. Staff, employees and third parties are required to lock screen or log off whenever they leave their workstation unattended. Use CTRL, ATL, DELETE.

8. All computers are password protected.

19. Distribution Records for Class 3 Medical Devices	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Confidentiality Agreement	

Policy Statement

This policy establishes guidelines and protocols for maintaining distribution records of Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure the traceability, accountability, and safety of Class 3 medical devices throughout their distribution lifecycle.

Scope:

This policy applies to all employees, contractors, and authorized personnel involved in the distribution of Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to the receipt, storage, handling, transportation, and final delivery of Class 3 medical devices.

Procedures

Record Keeping:

1. Distribution records must be maintained in a secure, organized, and easily retrievable manner, ensuring protection against loss, damage, or unauthorized access.

2. Distribution records should be kept for a minimum of [insert required retention period] in compliance with Health Canada regulations or any other applicable laws or regulations.

3. Distribution records should include, but are not limited to, the following information:
    a. Name, model, and description of the Class 3 medical device.
    b. Manufacturer's name, address, and contact details.
    c. Lot or batch numbers, serial numbers, and expiration dates.
    d. Quantity received, shipped, and current inventory levels.
    e. Date of receipt, storage, handling, and distribution.
    f. Name and contact information of the recipient (if applicable).
    g. Chain of custody information, including details of any intermediaries involved in the distribution process.

Receipt and Acceptance:

1. Upon receipt of Class 3 medical devices, a detailed record should be created, documenting the date, time, and conditions of the delivery.

2. Any discrepancies, damage, or issues with the received Class 3 medical devices should be immediately reported to the appropriate personnel, and relevant documentation should be

updated accordingly.

Storage and Handling:

1. Class 3 medical devices must be stored in accordance with the manufacturer's instructions and any applicable regulations, ensuring proper environmental conditions, such as temperature and humidity control.

2. Handling procedures should be implemented to prevent damage, contamination, or any adverse impact on the quality and safety of the medical devices.

Transportation:

1. Class 3 medical devices should be transported in compliance with applicable transportation regulations, ensuring adequate protection against damage, contamination, and unauthorized access.

2. Transportation records should be maintained, documenting the date, time, mode of transportation, and any other relevant information for each shipment.

Recall and Traceability:

1. In the event of a product recall or other safety-related concern, distribution records should enable the swift identification and traceability of affected Class 3 medical devices.

2. The distribution records should support the effective communication of information to relevant stakeholders, including Health Canada, manufacturers, customers, and other entities involved in the distribution chain.

Training and Awareness:

1. Employees involved in the distribution of Class 3 medical devices should receive appropriate training on this policy, relevant procedures, and regulatory requirements.

2. Regular awareness programs and updates should be conducted to ensure ongoing compliance with the Distribution Records Policy.

Responsibilities:

1. All individuals involved in the distribution of Class 3 medical devices have a responsibility to adhere to this policy. The Office Manager is responsible for overseeing the implementation and maintenance of the Distribution Records Policy.

20. Complaint Handling Regarding Class 3 Devices	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
This policy establishes guidelines and protocols for the effective and timely handling of complaints related to Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure that all complaints are promptly addressed, thoroughly investigated, and appropriate actions are taken to mitigate risks and improve product quality and safety.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the handling and resolution of complaints regarding Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to the receipt, documentation, investigation, resolution, and reporting of complaints.

Procedures:

Complaint Receipt:
1. All complaints related to Class 3 medical devices received by [Company/Organization Name] should be recorded, regardless of the source, including but not limited to customers, healthcare professionals, regulatory authorities, or internal staff.

2. Complaints should be acknowledged and assigned a unique identifier to facilitate tracking and monitoring throughout the complaint handling process.

3. Complaints should be promptly forwarded to the appropriate department or personnel responsible for complaint handling.

Investigation and Evaluation:
1. Complaints should be thoroughly investigated to determine the nature, extent, and root cause of the issue.

2. Relevant documentation, such as product information, manufacturing records, quality control records, and any other supporting data, should be collected and reviewed during the investigation.

3. The investigation should be conducted in a timely manner, and any necessary corrective and preventive actions should be identified and implemented.

Risk Assessment:
1. Complaints should be assessed for potential risks to patient safety, product performance, or regulatory compliance.

2. The risk assessment should consider factors such as the severity of the issue, the

likelihood of recurrence, and the potential impact on patients, users, or other stakeholders.

3. Risk mitigation strategies, including corrective actions, should be determined based on the outcome of the risk assessment.

Resolution and Communication:

1. Complaints should be resolved in a manner that is fair, timely, and satisfies customer expectations.

2. Customers should be provided with regular updates regarding the progress and resolution of their complaints.

3. Communication with customers should be clear, concise, and professional, ensuring that confidentiality and privacy requirements are maintained.

Documentation and Reporting:

1. All complaint handling activities, including investigations, actions taken, and outcomes, should be thoroughly documented and maintained as part of the complaint file.

2. Adverse events, serious incidents, or other reportable events identified during the complaint handling process should be promptly reported to Health Canada in accordance with applicable regulatory requirements.

3. Complaint trends and relevant metrics should be periodically analyzed and reported to management for review and continuous improvement purposes.

Training and Awareness:

1. Employees involved in the complaint handling process should receive appropriate training on this policy, relevant procedures, and regulatory requirements.

2. Regular awareness programs and updates should be conducted to ensure ongoing compliance with the Complaint Handling Policy.

Responsibilities:

All individuals involved in the handling of complaints related to Class 3 medical devices have a responsibility to adhere to this policy. The Office Manager is responsible for overseeing the implementation and maintenance of the Complaint Handling Policy.

Non-Compliance:

Non-compliance with this policy may result in disciplinary action, up to and including termination of employment or legal consequences, as deemed appropriate by Canada Filler Mart, INC, O/A Dermal Distributors Outlet.

21. Recalls of Class 3 Medical Devices	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
This policy establishes guidelines and protocols for the implementation and management of recalls for Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure the prompt and effective communication, coordination, and execution of recalls to protect public health and safety.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the recall process of Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to the identification, classification, communication, execution, and documentation of recalls.

Procedures:

Recall Management:
1. Recalls of Class 3 medical devices shall be managed in compliance with Health Canada regulations and guidelines, as well as any other applicable laws and regulations.

2. The recall process shall be initiated promptly when there is evidence that a Class 3 medical device may present a risk to the health and safety of patients, users, or other individuals.

3. A designated Recall Coordinator or team shall be responsible for overseeing and coordinating all recall activities, ensuring effective communication and collaboration with relevant stakeholders.

Recall Classification:
1. Recalls shall be classified based on Health Canada's guidelines for the severity of the potential risk posed by the Class 3 medical device. The classifications may include, but are not limited to, Class I, Class II, or Class III recalls.

2. The classification of a recall shall consider factors such as the likelihood and severity of potential harm, the population affected, and the availability of mitigating measures.

Communication:
1. Health Canada shall be notified of all recalls in accordance with regulatory requirements and timelines.

2. Effective communication channels shall be established to notify affected customers, healthcare professionals, distributors, and any other relevant stakeholders of the recall. Communication shall be clear, timely, and include instructions for appropriate actions to be

taken.

3. All communication related to the recall, including records of notifications and responses, shall be appropriately documented and maintained.

Execution and Follow-Up:

1. Recall execution shall include the retrieval, quarantine, and appropriate disposition of the affected Class 3 medical devices, in accordance with Health Canada's guidelines and any other applicable requirements.

2. Adequate systems and procedures shall be in place to track and monitor the progress of the recall, ensuring that all necessary actions are taken within specified timeframes.

3. All actions taken during the recall process, including updates to affected product labeling, documentation of corrective actions, and verification of their effectiveness, shall be thoroughly documented and retained.

Training and Awareness:

1. Employees involved in the recall process shall receive appropriate training on this policy, relevant procedures, and regulatory requirements.

2. Regular awareness programs and updates shall be conducted to ensure ongoing compliance with the Recalls Policy.

Post-Recall Evaluation:

1. Following the completion of a recall, a comprehensive evaluation shall be conducted to assess the effectiveness of the recall process, identify areas for improvement, and implement necessary corrective actions.

2. Lessons learned from the recall shall be documented and shared with relevant stakeholders to enhance future recall preparedness and execution.

22. Incident Reporting for Class 3 Medical Devices	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023
Template: Confidentiality Agreement	

Policy Statement:
This policy establishes guidelines and protocols for the reporting of incidents related to Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure the timely and accurate reporting of incidents to facilitate risk assessment, investigation, and appropriate actions to mitigate potential risks and enhance patient safety.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the reporting and management of incidents related to Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to the identification, documentation, assessment, reporting, and follow-up of incidents.

Procedures:

Incident Reporting Obligations:

1. All incidents involving Class 3 medical devices shall be promptly reported to the appropriate personnel in accordance with Health Canada's regulations and guidelines, as well as any other applicable laws or regulations.

2. Incidents that should be reported include, but are not limited to, malfunctions, device-related adverse events, product defects, off-label use, and any other issues that may pose a risk to patient safety or compromise device performance.

3. The reporting obligations apply to incidents occurring within the organization, as well as incidents reported externally by healthcare professionals, customers, regulatory authorities, or other sources.

Incident Documentation:

1. Incidents shall be documented in a consistent, accurate, and comprehensive manner, ensuring that all relevant details are recorded.

2. Incident reports should include information such as the date, time, location, description of the incident, individuals involved, and any available supporting evidence or documentation.

3. All incident documentation should be retained securely and confidentially, in compliance with applicable privacy and data protection laws.

Risk Assessment and Investigation:

1. Reported incidents shall be promptly assessed to determine the potential risks to patient safety, device performance, or regulatory compliance.

2. A thorough investigation should be conducted to identify the root cause(s) of the incident, utilizing appropriate resources and expertise as necessary.

3. Documentation of the risk assessment and investigation process, including findings and conclusions, should be maintained for future reference.

Reporting to Health Canada:

1. Incidents that meet the criteria for reporting to Health Canada shall be promptly submitted in accordance with regulatory requirements and timelines.

2. The reporting process should include the provision of accurate and complete information, ensuring that all mandatory fields and documentation are included.

3. Ongoing communication with Health Canada should be maintained throughout the incident management process, including updates, additional information, or any requested follow-up actions.

Corrective Actions and Follow-Up:

1. Appropriate corrective and preventive actions shall be determined based on the outcome of the risk assessment and investigation.

2. Actions taken to address the incident, including changes to device design, labeling, manufacturing processes, or quality control procedures, should be documented, implemented, and monitored for effectiveness.

3. Follow-up activities, such as tracking and documenting the implementation of corrective actions, should be performed to ensure that the identified risks have been adequately addressed.

Training and Awareness:

1. Employees involved in incident reporting and management shall receive appropriate training on this policy, relevant procedures, and regulatory requirements.

2. Regular awareness programs and updates shall be conducted to ensure ongoing compliance with the Incident Reporting Policy.

Responsibilities:

All individuals within Dermal Distributors Outlet have a responsibility to adhere to this policy and promptly report incidents related to Class 3 medical devices. The Office Manager is responsible for overseeing the implementation and maintenance of the Incident Reporting Policy.

23. Serious Risk of Injury to Human Health	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
This policy establishes guidelines and protocols for the identification, assessment, communication, and management of serious risks of injury to human health associated with Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure the prompt recognition and effective response to serious risks, prioritizing patient safety and mitigating potential harm.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the identification, evaluation, reporting, and management of serious risks of injury to human health associated with Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to risk assessment, communication, risk management, and ongoing monitoring of serious risks.

Procedures:

Risk Identification:
1. Adequate systems and procedures shall be in place to identify and assess potential serious risks of injury to human health associated with Class 3 medical devices.

2. Sources of information for risk identification may include adverse event reports, clinical studies, post-market surveillance data, published literature, and other relevant sources.

3. Vigilance systems and continuous monitoring mechanisms shall be implemented to proactively identify emerging serious risks and promptly evaluate their potential impact.

Risk Assessment:
1. Identified serious risks shall be assessed in terms of their severity, likelihood of occurrence, and potential impact on patient safety and public health.

2. Risk assessment shall consider factors such as the nature of the risk, the affected patient population, and the potential consequences of exposure or device failure.

3. Risk assessments shall be conducted by qualified personnel, utilizing appropriate tools, methodologies, and expertise.

Risk Communication:
1. Health Canada shall be notified promptly of serious risks in accordance with regulatory requirements and timelines.

2. Effective communication channels shall be established to notify healthcare professionals, customers, and other relevant stakeholders of serious risks, providing clear and concise information on potential adverse effects and recommended actions.

3. Ongoing communication with Health Canada and other regulatory authorities shall be maintained throughout the risk management process, including updates, additional information, or any requested follow-up actions.

Risk Management and Mitigation:

1. Appropriate risk management strategies and actions shall be determined based on the outcome of risk assessments, aiming to minimize or eliminate the identified serious risks.

2. Risk mitigation measures may include, but are not limited to, product labeling updates, changes in indications for use, modifications to manufacturing processes, enhanced quality control procedures, or product recalls if necessary.

3. All risk management activities and measures taken to address serious risks shall be thoroughly documented and maintained as part of the risk management file.

Post-Market Surveillance:

1. Ongoing post-market surveillance and monitoring systems shall be established to detect, evaluate, and respond to any new information regarding serious risks associated with Class 3 medical devices.

2. The data obtained through post-market surveillance activities shall be analyzed regularly to identify trends, potential safety signals, and emerging serious risks.

3. Actions based on post-market surveillance findings, such as additional risk assessments, safety communications, or further risk management activities, shall be promptly implemented as necessary.

Training and Awareness:

1. Employees involved in the identification, assessment, reporting, and management of serious risks shall receive appropriate training on this policy, relevant procedures, and regulatory requirements.

2. Regular awareness programs and updates shall be conducted to ensure ongoing compliance with the Serious Risk of Injury to Human Health Policy.

Responsibilities:

All individuals within Dermal Distributors Outlet have a responsibility to adhere to this policy and promptly report incidents related to Class 3 medical devices. The Office Manager is responsible for overseeing the implementation and maintenance of the Incident Reporting Policy.

24. Servicing	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
This policy establishes guidelines and protocols for the servicing and maintenance of Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure that servicing activities are performed safely, effectively, and in compliance with applicable standards, resulting in the continued performance and reliability of Class 3 medical devices.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the servicing and maintenance of Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to servicing, repairs, calibration, and preventive maintenance.

Procedures:

Servicing Personnel and Training:
1. Servicing activities shall be performed by qualified personnel who have the necessary knowledge, skills, and training to handle Class 3 medical devices.

2. Training programs shall be implemented to ensure that servicing personnel are familiar with the specific devices they service, as well as relevant procedures, safety precautions, and applicable regulations.

3. Training records and qualifications of servicing personnel shall be maintained and regularly reviewed to ensure ongoing competence.

Servicing Procedures:
1. Standardized servicing procedures shall be established and documented for each type of Class 3 medical device serviced.

2. Servicing procedures shall include step-by-step instructions, safety precautions, equipment and tools required, and any specific requirements for calibration or verification.

3. The servicing procedures shall be regularly reviewed and updated to reflect changes in technology, best practices, or regulatory requirements.

Equipment and Facilities:
1. Adequate equipment, tools, and facilities shall be provided to support servicing activities and ensure the proper functioning of Class 3 medical devices.

2. Servicing equipment and tools shall be calibrated, maintained, and periodically verified for accuracy and reliability.

3. Facilities used for servicing activities shall be designed, maintained, and controlled to prevent contamination, damage, or any adverse impact on the devices being serviced.

Documentation and Record Keeping:

1. All servicing activities shall be thoroughly documented, including the date, details of the servicing performed, parts replaced, calibration results, and any other relevant information.

2. Service records shall be maintained for each serviced Class 3 medical device, allowing for traceability and retrieval of information.

3. Service records shall be securely stored and retained for the duration specified by applicable regulatory requirements.

Adverse Events and Complaints:

1. Any adverse events, incidents, or complaints related to the servicing of Class 3 medical devices shall be promptly reported, documented, and investigated.

2. Corrective actions shall be taken in response to adverse events or complaints, aiming to prevent recurrence and improve the quality and safety of servicing activities.

3. Adverse events and complaints related to servicing shall be reported to Health Canada in accordance with regulatory requirements.

Quality Management:

1. Servicing activities shall be conducted in accordance with the principles of a robust quality management system, ensuring adherence to applicable standards, regulations, and best practices.

2. Regular quality audits and reviews shall be conducted to assess the effectiveness of the servicing process, identify areas for improvement, and implement necessary corrective actions.

3. Continuous training and awareness programs shall be implemented to promote a culture of quality and continuous improvement in servicing activities.

Responsibilities:

All individuals involved in the servicing and maintenance of Class 3 medical devices have a responsibility to adhere to this policy. The [insert job title] is responsible for overseeing the implementation and maintenance of the Servicing Policy.

Non-Compliance:

Non-compliance with this policy may result in disciplinary action, up to and including termination of employment or legal consequences, as deemed appropriate by Dermal Distributors Outlet.

25. Corrective Action	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement:
This policy establishes guidelines and protocols for implementing effective corrective actions related to Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure that identified nonconformities, deficiencies, or deviations are promptly addressed, mitigating risks, and improving the safety and performance of Class 3 medical devices.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the identification, evaluation, implementation, and monitoring of corrective actions related to Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities associated with root cause analysis, corrective action planning, implementation, and verification.

Policy Guidelines:

Identification of Nonconformities:
1. Nonconformities, deficiencies, or deviations related to Class 3 medical devices shall be promptly identified through various sources, including complaints, adverse events, internal audits, post-market surveillance, and quality control processes.

2. An effective system shall be in place to capture, document, and evaluate nonconformities, ensuring that they are properly investigated and categorized.

3. Nonconformities shall be assessed to determine their potential impact on patient safety, device performance, regulatory compliance, or customer satisfaction.

Root Cause Analysis:
1. Root cause analysis techniques, such as the Five Whys, fishbone diagrams, or other appropriate methodologies, shall be employed to determine the underlying causes of nonconformities.

2. Root cause analysis shall be conducted in a systematic and structured manner, involving relevant stakeholders and subject matter experts as necessary.

3. The objective of root cause analysis is to identify the underlying factors contributing to the nonconformity, rather than focusing solely on the symptoms or immediate causes.

Corrective Action Planning:
1. Based on the findings of the root cause analysis, corrective actions shall be planned to address the identified nonconformities and prevent their recurrence.

2. Corrective action plans shall be documented and include clear objectives, actions to be

taken, responsible parties, timelines, and resource requirements.

3. Corrective actions shall be proportionate to the risks associated with the nonconformities, considering the severity of potential harm and the likelihood of recurrence.

Corrective Action Implementation:

1. Corrective actions shall be implemented in a timely and effective manner, following the approved corrective action plan.

2. Implementation of corrective actions may involve activities such as design changes, process improvements, training programs, supplier notifications, or other necessary actions to address the identified nonconformities.

3. Adequate resources, expertise, and support shall be provided to facilitate the successful implementation of corrective actions.

Verification and Effectiveness:

1. The effectiveness of corrective actions shall be evaluated through appropriate verification activities, such as testing, inspections, audits, or other suitable methods.

2. Verification activities shall be conducted to ensure that the implemented corrective actions have effectively addressed the identified nonconformities and have not introduced new issues.

3. The results of verification activities shall be documented and assessed to confirm the successful resolution of nonconformities.

Documentation and Record Keeping:

1. All activities related to corrective actions, including the identification of nonconformities, root cause analysis, corrective action planning, implementation, and verification, shall be thoroughly documented.

2. Corrective action records shall be maintained, including details of the nonconformities, corrective action plans, implementation activities, verification results, and any associated communications.

3. Corrective action records shall be securely stored and retained for the duration specified by applicable regulatory requirements.

25. Installation	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
This policy establishes guidelines and protocols for the installation of Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure that installations are carried out safely, efficiently, and in compliance with relevant standards and guidelines, thereby ensuring the proper functioning and performance of Class 3 medical devices.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the installation of Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to the planning, preparation, execution, and verification of installations.

Procedures:

Pre-Installation Planning:
1. Prior to installation, a thorough assessment shall be conducted to determine the specific requirements and considerations for each Class 3 medical device to be installed.

2. Installation plans shall be developed, considering factors such as the device specifications, physical location, infrastructure requirements, electrical connections, safety measures, and any other relevant considerations.

3. Adequate resources, including trained personnel, tools, and equipment, shall be allocated to ensure the successful execution of installations.

Installation Procedures:
1. Standardized installation procedures shall be developed and documented for each type of Class 3 medical device, incorporating manufacturer's instructions, regulatory requirements, and industry best practices.

2. Installation procedures shall outline the step-by-step process, safety precautions, sequence of tasks, and any specific requirements for calibration, verification, or testing.

3. Installation procedures shall be regularly reviewed and updated to reflect changes in technology, best practices, or regulatory requirements.

Qualified Personnel:
1. Installation activities shall be carried out by qualified personnel who have the necessary knowledge, skills, and training to install Class 3 medical devices safely

and effectively.

2. Training programs shall be implemented to ensure that installation personnel are familiar with the specific devices they install, as well as relevant procedures, safety precautions, and applicable regulations.

3. Training records and qualifications of installation personnel shall be maintained and regularly reviewed to ensure ongoing competence.

Verification and Testing:

1. Following the installation, verification and testing activities shall be conducted to ensure the proper functioning and performance of the installed Class 3 medical device.

2. Verification and testing shall be conducted according to established protocols, which may include functional testing, calibration checks, performance evaluations, or other appropriate methods.

3. The results of verification and testing activities shall be documented and assessed to confirm that the installation has been successfully completed and the device is operating as intended.

Documentation and Record Keeping:

1. All installation activities shall be thoroughly documented, including the date, details of the installation, verification and testing results, and any other relevant information.

2. Installation records shall be maintained for each installed Class 3 medical device, allowing for traceability, retrieval of information, and support of future maintenance or servicing activities.

3. Installation records shall be securely stored and retained for the duration specified by applicable regulatory requirements.

Post-Installation Evaluation:

1. After the installation, a post-installation evaluation shall be conducted to assess the effectiveness of the installation process and identify any opportunities for improvement.

2. Feedback and observations from installation personnel, end-users, or other stakeholders shall be collected and analyzed to identify lessons learned and address any issues or concerns.

3. Findings from the post-installation evaluation shall be used to refine installation procedures, enhance training programs, and improve the overall installation process.

26. Handling, Storage, Delivery	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement
This policy establishes guidelines and protocols for the handling, storage, and delivery of Class 3 medical devices in accordance with Health Canada's regulations and requirements. The purpose of this policy is to ensure that Class 3 medical devices are handled, stored, and delivered in a manner that preserves their quality, safety, and effectiveness throughout the supply chain.

Scope:
This policy applies to all employees, contractors, and authorized personnel involved in the handling, storage, and delivery of Class 3 medical devices within Dermal Distributors Outlet. It encompasses all activities related to receiving, inspection, storage, inventory management, packaging, labeling, and transportation.

Procedures:

Receiving and Inspection:
1. Upon receipt of Class 3 medical devices, a receiving and inspection process shall be implemented to verify the accuracy, integrity, and condition of the received items.

2. Incoming shipments shall be compared against purchase orders, invoices, or delivery notes to ensure that the correct devices, quantities, and specifications have been received.

3. Class 3 medical devices shall be inspected for any visible damage, tampering, or discrepancies, and appropriate actions shall be taken to address any issues identified.

Storage and Inventory Management:
1. Class 3 medical devices shall be stored in accordance with the manufacturer's instructions, applicable regulations, and best practices for temperature, humidity, lighting, and other relevant environmental conditions.

2. Adequate storage facilities and infrastructure shall be provided to ensure the proper segregation, organization, and protection of Class 3 medical devices.

3. Inventory management systems and procedures shall be implemented to track stock levels, expiration dates, lot numbers, and other relevant information to prevent the use of expired or compromised devices.

Handling and Packaging:
1. Class 3 medical devices shall be handled with care to prevent damage or contamination during storage, retrieval, and transport.

2. Proper handling techniques and equipment shall be used, such as gloves, sterile packaging, or other appropriate measures, to maintain the cleanliness and integrity of the devices.

3. Packaging materials used for Class 3 medical devices shall be suitable for the intended purpose, ensuring adequate protection and preventing damage during storage and transportation.

Labeling and Identification:

1. Class 3 medical devices shall be appropriately labeled and identified to ensure accurate tracking, traceability, and compliance with regulatory requirements.

2. Labels shall include essential information such as device name, lot number, expiration date, storage conditions, and any other relevant details as required by applicable regulations.

3. Labels and identification markings shall be clear, legible, and resistant to fading or damage during handling, storage, and transportation.

Transportation and Delivery:

1. Class 3 medical devices shall be transported and delivered in accordance with applicable transportation regulations, ensuring the preservation of their quality, safety, and sterility.

2. Transportation vehicles, containers, and packaging used for Class 3 medical devices shall be appropriate for the nature of the devices and provide adequate protection against physical damage, temperature variations, humidity, or any other factors that may compromise their integrity.

3. Delivery personnel shall be trained on the proper handling and storage of Class 3 medical devices and follow designated procedures to ensure timely and secure deliveries.

Quality Control and Monitoring:

1. Quality control measures shall be implemented to monitor the handling, storage, and delivery of Class 3 medical devices, including periodic inspections, temperature monitoring, or other suitable methods.

2. Records of handling, storage, and delivery conditions, including temperature logs, inspection reports, and any relevant documentation, shall be maintained as required by applicable regulations.

3. Nonconformities, deviations, or incidents related to the handling, storage, or delivery of Class 3 medical devices shall be promptly investigated, documented, and addressed according to established procedures.

28. Terms and Conditions.	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Terms and Conditions

Welcome to Dermal Distributors Outlet! These terms and conditions outline the rules and regulations for using our wholesale online dermal fillers retail platform, located at www.dermaldistributorsoutlet.com. By accessing this website, we assume you accept these terms and conditions in full. Do not continue to use Dermal Distributors Outlet if you do not agree with all the terms and conditions stated on this page.

1. Definitions

"Dermal Distributors Outlet," "we," "us," or "our" refers to the wholesale online dermal fillers retailer.
"Customer," "you," or "your" refers to any individual or entity accessing or using our website to purchase dermal fillers.
"Products" refers to the dermal fillers available for wholesale purchase on our website.

2. Wholesale Account

2.1 To access our wholesale prices and place orders for dermal fillers, you must create a wholesale account with Dermal Distributors Outlet.

2.2 You must provide accurate and up-to-date information when creating your wholesale account, including company details, contact information, and a valid resale certificate or business license.

2.3 Dermal Distributors Outlet reserves the right to approve or decline wholesale accounts at its sole discretion.

3. Ordering Process

3.1 Once your wholesale account is approved, you may browse our product catalog and place orders for dermal fillers.

3.2 By placing an order, you confirm that you are a certified practitioner and are authorized to purchase and administer dermal fillers in your jurisdiction.

4. Product Information

4.1 We make every effort to provide accurate and detailed product information on our website. However, Dermal Distributors Outlet does not warrant or guarantee the accuracy, completeness, or reliability of any product descriptions or information.

4.2 Dermal Distributors Outlet reserves the right to update product information, prices, and availability without prior notice.

5. Payment

5.1 All orders must be paid in full at the time of purchase.

5.2 We accept various payment methods, including credit/debit cards and bank transfers. Payment options may vary based on your location.

6. Shipping and Delivery

6.1 Dermal Distributors Outlet aims to process and ship orders promptly. However, shipping times may vary depending on the destination and other factors beyond our control.

6.2 Shipping costs are calculated based on the delivery address and the chosen shipping method.

6.3 Customers are responsible for ensuring that their delivery address is accurate and complete. Dermal Distributors Outlet will not be liable for any delivery issues arising from incorrect address details provided by the customer.

7. Returns and Refunds

7.1 Dermal Distributors Outlet does not accept returns for dermal fillers due to their medical nature.

7.2 In the event of a defective or damaged product, please contact our customer support within 7 days of receipt to arrange for a replacement or refund.

8. Compliance with Laws

8.1 By using our website and purchasing dermal fillers, you agree to comply with all applicable laws and regulations governing the purchase, sale, and use of dermal fillers in your jurisdiction.

9. Limitation of Liability

9.1 Dermal Distributors Outlet will not be liable for any direct, indirect, incidental, special, or consequential damages resulting from the use or inability to use our website or products.

10. Governing Law

10.1 These terms and conditions are governed by and construed in accordance with the laws of Health Canada and the FDA.

11. Modifications

11.1 Dermal Distributors Outlet reserves the right to modify these terms and conditions at any time without prior notice. Please review this document regularly for updates.

By using Dermal Distributors Outlet's website and purchasing products, you acknowledge that you have read, understood, and agree to these terms and conditions.

29. Return Policy	
Policy Author: Corey Ralph	**Effective and Revision Dates:** April 2023

Policy Statement:
This policy establishes the return guidelines and protocols for customers purchasing dermal fillers from Dermal Distributor Outlet. The purpose of this policy is to ensure a fair and efficient return process for customers, while maintaining compliance with regulatory requirements and ensuring the safety and integrity of our products.

Scope:
This policy applies to all customers who purchase dermal fillers from Dermal Distributor Outlet. It encompasses all activities related to the initiation, authorization, processing, and disposition of returns for dermal filler products.

Policy Guidelines

Return Eligibility:
1.1. Returns of dermal filler products shall be accepted in accordance with applicable regulations and guidelines, which may include reasons such as product defects, shipping errors, or customer dissatisfaction due to product quality or performance.

1.2. The eligibility criteria for returns shall be clearly defined, communicated, and documented to ensure consistency and compliance with regulatory requirements.

1.3. Returns that do not meet the eligibility criteria may be denied or subject to alternative resolution options, as deemed appropriate by Dermal Distributor Outlet.

Return Authorization:
2.1. Customers requesting a return of dermal filler products shall follow a designated process to obtain return authorization.

2.2. Return authorization requests shall be submitted to Dermal Distributor Outlet within the specified time period, accompanied by relevant documentation, such as the original purchase receipt or invoice.

2.3. Authorized personnel from Dermal Distributor Outlet shall review the return authorization requests and determine their eligibility based on the established criteria.

Return Process:
3.1. Customers shall follow the prescribed return process as outlined by Dermal Distributor Outlet to ensure the efficient and secure return of dermal filler products.

3.2. Customers shall be provided with clear instructions on packaging requirements, documentation, and any specific return procedures to facilitate the safe and proper return of the products.

3.3. Return documentation, such as a return form, shall be completed accurately by the customer, capturing essential information about the returned product, reason for return, and any relevant details.

Evaluation and Assessment:
4.1. Upon receipt of the returned dermal filler product, an evaluation and assessment process shall be conducted to determine the appropriate disposition.

4.2. The returned product shall be inspected, visually examined, and assessed based on established procedures to evaluate its condition, integrity, and compliance with quality standards.

4.3. Qualified personnel from Dermal Distributor Outlet shall be responsible for conducting evaluations and assessments, documenting their findings, and making recommendations for further actions, such as replacement, refund, or disposal.

Disposition and Refunds:
5.1. The disposition of returned dermal filler products shall be determined based on the results of the evaluation and assessment process, regulatory requirements, and customer preferences.

5.2. Dermal Distributor Outlet shall take appropriate actions, which may include offering replacements, issuing refunds, or providing credits for future purchases, based on the nature of the return and the customer's preferences.

5.3. Refunds, when applicable, shall be processed promptly and in accordance with established procedures, ensuring accurate reimbursement to the customer.

Communication:
6.1. Dermal Distributor Outlet shall communicate the outcome of the return request to the customer, including information on the disposition of the product and any applicable actions taken.

6.2. Communication with customers shall be conducted professionally, courteously, and in compliance with applicable privacy and confidentiality requirements.

Responsibilities:
All customers purchasing dermal fillers from Dermal Distributor Outlet have a responsibility to familiarize themselves with this return policy and follow the prescribed procedures.

Glossary

"Access" means to obtain or retrieve information

- **Access** may be used in relation to the client's right to review and/or obtain a copy of his or her medical record
- **Access** may be used in relation to the act of viewing information in the EMR

"Agent" means a person that with the approval of the trustee acts for or on behalf of the trustee in respect to personal and business information and only for the purpose of the trustee and not the agent's purpose whether or not the agent has the authority to bind the trustee, is paid by the trustee, or is remunerated by the trustee.

"**Breach**" means an unauthorized collection, use or disclosure of personal and business information

"Collect" means to gather, obtain access to, acquire, receive, or obtain personal and business information from any source by any means

"Confidentiality" means the obligation of the person or organization collecting or using the information to not reveal it to anyone who is not authorized to know it

"Control" means the power or authority to manage, restrict, regulate or administer the collection, use, or disclosure of the record[1].

"Custody" means the physical and/or legal responsibility for the collection, use, disclosure of the personal and business information.

"De-identified personal and business information" means personal and business information from which any information that may reasonably be expected to identify an individual has been removed. This includes information that has been aggregated or transformed so that it cannot reasonably be re-identified.

"Designated archive" means an archive designated in the regulations of HIA.

"Disclose" (or disclosure) means to transfer or release information to another person or organization separate entity outside of the trustee's authority.

"Information and Privacy Commissioner of Alberta" (OIPC) means an independent officer of the Alberta Legislative Assembly who oversees three different Alberta privacy and/or access statutes.

"Information management service provider"(IMSP) means a person who or body that processes, stores, archives or destroys records of a trustee containing personal and business information or that provides information management or information technology services to a trustee with respect to records of the trustee containing

personal and business information, and includes a trustee that carries out any of those activities on behalf of another trustee, but does not include a trustee that carries out any of those activities on its own behalf.

"**Integrity**" means the assurance that personal and business information has not been modified, or in some other way interfered with such that the nurse practitioners, and certified technicians or client does not consider the information reliable. This includes throughout the storage, use, transfer and retrieval of the personal and business information.

"Personal and business information" means, with respect to an individual, whether living or deceased:

- Information with respect to the physical or mental health of the individual
- Information with respect to any health service provided to the individual
- Information with respect to the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual
- Information that is collected
    - in the course of providing health services to the individual; or
    - incidentally to the provision of health services to the individual;
- Registration information

"Primary purpose" means the purpose for which personal and business information was originally collected, and includes any purpose that is consistent with that purpose.

"Privacy" means a broad concept, which involves the right of the individual to exercise a measure of control over his or her personal and business information. It involves the decision of the individual about what personal and business information will be disclosed to a trustee and for what purposes. It captures both security and confidentiality, which are subsets of privacy.

"**Privacy Officer**" means a person designated to make decisions or form opinions required under HIA.

"Record" means a record of information in any form and includes information that is written, photographed, recorded, digitized, or stored in any manner, but does not include computer programs or other mechanisms that produce records.

"Registration information" means information about an individual that is collected for registering the individual for the provision of health services, and includes the individual's health services number and any other number assigned to the individual as part of a system of unique identifying numbers that is prescribed in the regulations.

"Secondary purpose" means the use or disclosure of information for a purpose other than that for which it was originally collected, which is a program activity or service

related to client care. An example is the collection, use, and disclosure of personal and business information for billing purposes.

"Security" means the procedures and systems used to restrict access, and to protect and maintain the integrity of the personal and business information.

"**Third Parties**" means individuals and organizations who provide a service to the practice that does, or has a significant chance of, seeing or using personal and business information, but who are not trustees, employees, professionals, medical students, residents.

"Trustee" means any of the following that have custody or control of personal and business information as defined in HIA.

"Use" includes reference to or manipulation of personal and business information by the trustee that has custody or control of the information, but does not include disclosure to another person or trustee.

Acronyms

CRM – Client Resource Management

IMA – Information Management Agreement

OIPC – Office of the Information and Privacy Commissioner of

Alberta PIP – Pharmaceutical Information Program

PIPEDA – *Personal Information Protection and Electronic Documents Act*