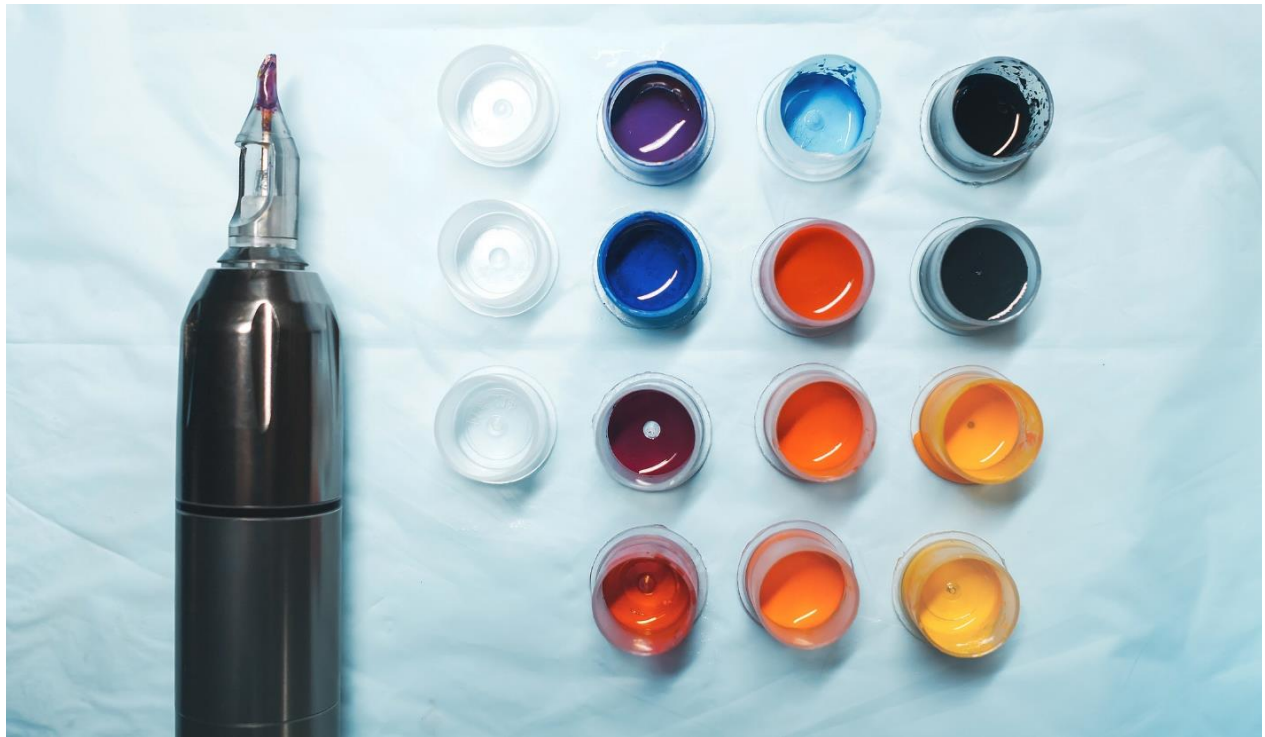


EVIDENCE BRIEF

Reprocessing Risks for Tattoo Cartridge Grips



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Key Messages

- Cartridge grips are different from traditional grips that house needle bars.
- Some cartridges contain a membrane that is capable of preventing the backflow of ink and blood between the cartridge and the machine body.
- There are several options to assess the effectiveness of the membrane in tattoo cartridges.
- Where a public health inspector is satisfied that the needle cartridge is effectively sealed by a membrane, cartridge grips may be classified as a non-critical item for the purposes of cleaning and disinfection.

Issue and Research Question

This evidence brief asks: **Is there a risk of infection associated with the use of low- or intermediate-level disinfection to reprocess tattoo cartridge grips?**

Overview

Tattoo cartridges are a newer innovation in tattooing. The first patents for a tattoo cartridge were filed by MT. DERM GmbH,^{1,2} also known as Cheyenne Professional Tattoo Equipment. They released their popular cartridge based tattoo machine, the HAWK in 2007.³ Unlike in a traditional tattoo system, where the needle rests within the grip (sometimes referred to as a needle holder, tube, or tip), cartridges contain the needles within a separate housing that fits inside of a different type of grip (sometimes referred to as a cartridge holder). Cartridge based tattoo machines are available in both a traditional rotary and pen-type configuration.

Figure 1. Cartridge Based Machine

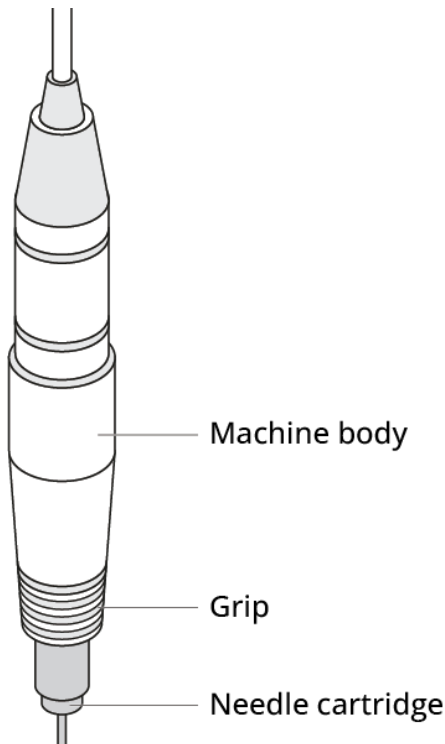
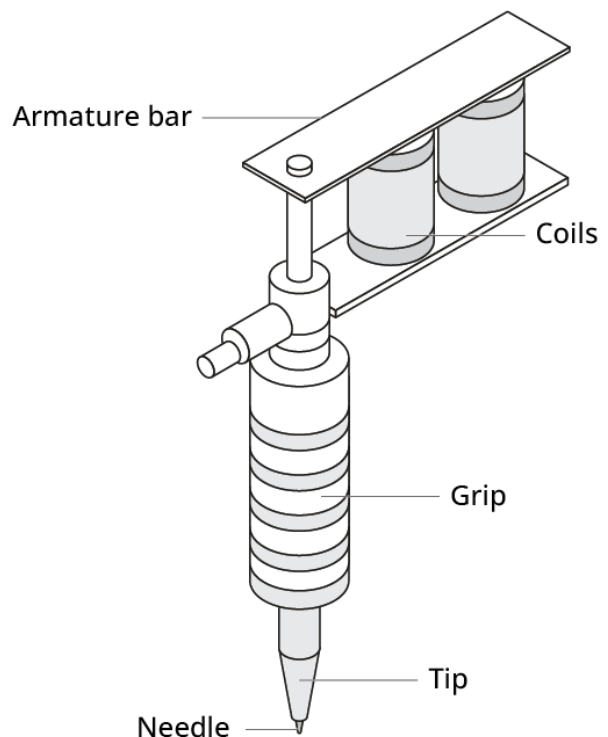


Figure 2. Traditional Tattoo Machine



In order to differentiate between the two different types of grips, this evidence brief will refer to them as “traditional grips” and “cartridge grips.”

Cartridge based systems are marketed as having several advantages over traditional tattoo systems, including:

- They allow artists to quickly swap between needle configurations.
- The needle can be retracted when not in use through the use of a membrane, magnet, or other mechanism to reduce the risk of injury.
- They can be equipped with a membrane that is sealed to effectively prevent liquid transfer into the cartridge grip and machine body, preventing the ingress of ink or body fluids.

Cartridge grips are largely interchangeable between machines and can be classified as re-usable or single-use disposable. Re-usable cartridge grips are typically made out of metal and are designed to withstand an autoclave. Disposable cartridge grips are available at a lower price-point and are intended to be single-use disposable. For some machines, the cartridge grips also doubles as a control to adjust the depth of the needles.

Disposable grip covers (e.g., grip tape or memory foam covers) are also available from several manufacturers but these are not to be confused with disposable cartridge grips as they are usually porous and serve a different function. They are intended to fit over top of the machine to make it comfortable for the tattoo artist to grasp.

Needle cartridges are also used in other applications that may not include a grip. These include micropigmentation and microneedling pens.

Classification

O. Reg 136/18: Personal Service Settings states:

Every operator of a personal service setting shall ensure that,

- (a) all equipment used in providing personal services at the setting is maintained in good repair and in a sanitary condition; and
- (b) all equipment used in providing personal services at the setting is,
 - (i) maintained in accordance with the manufacturer’s instructions, if any, or
 - (ii) if no manufacturer’s instructions are available, maintained in accordance with the directions, if any, of a medical officer of health or public health inspector.⁴

The *Guide to Infection Prevention and Control in Personal Service Settings* applies a version of Spaulding’s classification in personal service settings.^{5,6} Items are categorized based on their intended use and/or risk of contamination and assigned a minimum level of reprocessing. Instruments that penetrate the skin or enter sterile tissue are classified as critical items that require sterilization. Instruments that contact mucous membranes or non-intact skin but do not ordinarily penetrate the skin are classified as semi-critical items that require sterilization or high level disinfection. Instruments that do not directly contact the client or contact only hair or intact skin are classified as non-critical and require intermediate- or low-level disinfection.

Ontario has modified this classification system in a manner that is consistent with federal guidance.⁷ Items that hold, manipulate or contact critical items are treated the same as semi-critical items. Additionally, some tattoo, piercing, and body modification equipment with a high risk of transmission if contaminated are treated as critical items. Ontario guidance does not differentiate between traditional grips and cartridge grips. It treats reusable grips, tubes, and tips of tattoo machines as critical items that require sterilization due to the invasive nature of tattooing, the proximity of these items to punctured skin, and the significant risk for blood/body fluid contact.⁵

Previous Recommendations

When cartridge based machines first began to see widespread use in Ontario, Public Health Ontario (PHO) was asked to provide recommendations for their use. PHO conducted a jurisdictional scan, reviewed the manufacturer's instructions for use (MIFU) for the more established machines, and contacted the manufacturers directly. In 2018, PHO made the following recommendations:

1. Cartridge grips should be single-use disposable or autoclaved after each use, if classified as a multiuse device.
2. Only cartridges with a protective membrane should be used.
3. Operators should follow the MIFU when one is available.

Since 2018, questions regarding the reprocessing requirements for these machines have continued to be asked. Some public health units have reported pushback on these requirements from operators that would prefer to disinfect cartridge grips using a liquid disinfectant.

Methods

A research librarian in combination with a reviewer conducted a literature search in February of 2023. Medline, Embase, and ProQuest Public Health databases were searched for published literature, and an additional search for grey literature was conducted using Google and Google Scholar. The search was broadly focused outbreaks linked to tattooing and infection prevention and control (IPAC) considerations. The search yielded 213 full text studies from Medline, 307 from Embase, and 22 from ProQuest Public Health database. Duplicates were then removed, leaving 414 studies under consideration.

Search results were exported for a title and abstract review for eligibility. Provincial and international guidelines were consulted in order to assess differences in recommendations. Given the need to consider a wide scope of both peer reviewed and grey literature, full text versions of all potentially relevant articles were retrieved for review. Additional studies and supporting evidence were identified through hand-searching the reference lists of relevant studies, in addition to inclusion of any relevant legislation. The manufacturers of 27 different cartridge based tattoo machines were identified and their published materials on their websites, sales listings, and social media were reviewed for reprocessing instructions. In 16 instances, contact information for the manufacturer was available and PHO requested additional information on the risk of cross contamination between a re-usable grip and a tattoo cartridge, reprocessing recommendations, and recommendations for wrapping their tattoo machines.

Main Findings

The title and abstract scan yielded 23 relevant abstracts, which were then reviewed in full text. No articles addressed the research question outlined above. The user manuals for 9 cartridge based machines were obtained, 14 manufacturer affiliated YouTube pages were identified, and 2 manufacturers responded to PHOs request for information.

Manufacturer's Instructions for Use

Most of the user manuals obtained by PHO do not provide instructions for disinfecting or sterilizing the cartridge grip. *Cheyenne*'s user manual clearly indicates that if a grip is severely soiled, it should be cleaned in an ultrasonic cleaner and that whenever the grip is contaminated, it should be autoclaved for 20 minutes at a temperature of 121°C and a pressure of 2 bar.⁸ *Cheyenne* also has instructional videos on their YouTube page that instruct users to disinfect the grip with a liquid disinfectant.⁹ When questioned regarding the appropriate reprocessing technique, they responded by email on January 27, 2023 an indicated that both techniques were sufficient but that users should defer to their local regulations. *Helios Tattoo* does not have specific instructions in their user manual, but indicates that the hand piece must be wiped down with a soft disinfecting cloth but that the lower portion (the cartridge grip) may be autoclaved for sterilization.¹⁰

Two other manufacturers provide cleaning and disinfection instructions on their official *YouTube* page. *Bishop Rotary* demonstrates using a disinfectant wipe but instructs operators to consult with their local regulatory authority.¹¹ *FK Irons* provides instructions on using an autoclave but also refers to liquid disinfectants.¹² *CNC Tattoo* provides a written cleaning and disinfection guide on their website.¹³ They instruct users to use a cloth dipped in disinfectant but also indicate that an autoclave is the best choice.

Several manufacturers recommend that only cartridges with safety membranes be used. Membranes also prevent the flow of ink into the machine body and many warranties do not cover damages caused by ink inside of the machine.¹⁴⁻¹⁶ None of the MIFUs identified by PHO contained instructions for cleaning and disinfecting the inside of a machine that became contaminated as the result of a failed membrane.

Jurisdictional Scan

International regulations, standards, and guidelines with the traditional or cartridge grip specific reprocessing requirements were found for the European Union,¹⁷ Australia,¹⁸⁻²¹ New Zealand,²² England,²³ and the several US States.²⁴⁻³⁰ Some of these standards pre-date the common adoption of cartridge based tattoo machines. Where a reference to grips exists, they are universally required to be single-use disposable or sterilized after each use. With the exception of the European Union Standard *EN 17169:2020 Tattooing - Safe and hygienic practice*,¹⁷ none of the jurisdictions differentiate between traditional and cartridge grips. *EN 17169:2020* states:

“Where a needle cartridge is sealed to effectively prevent liquid transfer into the needle cartridge holder, such that there is no ingress of body fluids, the needle cartridge holder is not regarded as high-risk equipment. The needle cartridge holder shall be made safe for reuse by treatment with a suitable chemical disinfectant in accordance with the manufacturer’s instructions. It shall be the responsibility of the tattooist to obtain and retain documented proof from the supplier that the needle cartridge in use is effectively sealed.”¹⁷

In Canada, provincial regulations or guidelines were found for British Columbia,³¹ Alberta,³² Saskatchewan,³³ Manitoba,³⁴ Nova Scotia,³⁵ and PEI.³⁶ Federal guidance on tattoo grip reprocessing also exists.⁷ Alberta and Nova Scotia's guidance don't specifically reference grips but apply broad classifications of items and equipment that are consistent with Spaulding.⁶ Where a federal or provincial regulation or guideline specifically references a grip it is required to be single-use disposable or sterilized after each use. None of the identified federal or provincial regulations or guidelines currently differentiate between traditional grips and cartridge grips.

Several jurisdictions that do not list specific requirements for traditional cartridge grips instead rely upon instrument/equipment classifications that are similar to Spaulding's classification.^{32,35,37} The way that Spaulding's classification is applied to personal service settings varies from jurisdiction to jurisdiction. For example, while Nova Scotia's guidance³⁵ does not specifically mention grips, items that hold sterile items are classified as critical and requiring sterilization. Similarly, Scottish guidance³⁷ classifies equipment that is contaminated with particularly virulent or readily transmitted organisms as having an intermediate infection risk and recommends sterilization or disinfection.

In Ontario, three public health units have publicly available fact sheets that reference cartridge grips. When a needle cartridge with a membrane that prevents backflow is used, they permit the operator to disinfect the cartridge grip with a liquid disinfectant. Peel Public Health permits the use of a low level or intermediate disinfectant³⁸ while the Toronto Public Health permits the use of a disinfectant with a kill claim against mycobacteria.³⁹ Durham Region Health Department requires operators to obtain cartridges from a manufacturer that states "that the needle cartridge system has a backflow preventer, also known as a safety membrane or barrier, to prevent cross-contamination to be approved for use."⁴⁰ If a cartridge without a membrane is used, they require the grip to be sterile prior to use.⁴⁰

Risk of Contamination

None of the articles reviewed covered the risk of the traditional or cartridge grips becoming contaminated or the viral contamination of tattoo equipment. This lack of research was noted in one other article that conducted a review of the literature.⁴¹ No documented outbreaks that were caused by contaminated traditional or cartridge grips were identified.

None of the MIFUs addressed the risk of contamination. When contacted by PHO, *Cheyenne Tattoo* responded by email on January 27, 2023 indicating that a cartridge grip would most likely become contaminated if a cartridge without a membrane was used, or by dipping the cartridge too deep in the rinse solution.

Instructional videos produced by the manufacturers indicated that the cartridge grip could be contaminated when swapping between cartridges⁴² and during long tattoo sessions.⁴³ They also indicated the presence of small amounts of ink inside the cartridge grip was a possibility.^{9,12} *CNC Tattoo's* written guide also indicates that "Pen-type tattoo machines are more likely to leave ink and residue at the handle than traditional tattoo machines."¹³

Blood-borne Infection Risk

Several articles reviewed discussed the risk of blood-borne infections (BBI) and tattooing. Having tattoos is associated with a higher risk of BBIs.⁴⁴⁻⁴⁶ This increased risk remains after adjusting for other risk factors.⁴⁷ None of the studies documented specific elements of the tattooing process as being linked to BBI transmission; however, one study found that tattoo artists have a higher BBI risk than their clients.⁴⁸ The study found that almost one in five artists reported having a needlestick/cut injury and determined that this may account for the increased risk.⁴⁸

Effectiveness of the Membrane

Cartridges with membranes are available from a number of different manufacturers. Documentation provided by manufacturers indicates that not all brands of cartridges are the same size and that some cartridges are tighter than others. While at least one manufacturer provides publicly available documentation regarding the effectiveness of their membrane,⁴⁹ most manufacturers do not. The sale of needle cartridges is not regulated in Canada and it can be difficult to verify the efficacy of these products.

The European Union standard *EN 17169:2020 Tattooing - Safe and hygienic practice* provides three instructions to verify that cartridges are effectively sealed:

- The supplier shall be asked for cartridges with a physical barrier;
- The labelling shall be checked to confirm that a physical barrier is provided;
- Each cartridge type shall be tested by filling one cartridge sample with fluid (e.g., tattoo ink) and operating the back-end plunger while the tip is in upright position for at least 50 times to look for signs of leakage through the plunger.¹⁷

Additionally, the presence of ink inside of a used cartridge grip or machine body that has only contained one cartridge may be evidence of a membrane that is not forming a tight seal.

Discussion and Conclusions

There is a lack of evidence surrounding the risk of contaminated cartridge grips and contaminated tattoo equipment in general. There is limited guidance regarding and evidence surrounding the efficacy of the membranes that are found in needle cartridges and that evidence may not be generalizable to all needle cartridges. While the earliest manufacturer of cartridge based tattoo machines still indicates that contaminated grips must be sterilized in their user manual, other documents indicate that artists have a choice based on their local regulations. Because of this uncertainty, the use of single-use disposable cartridge grip remains the safest option followed by the proper pre-cleaning, disassembly, cleaning, sterilization, and storage of cartridge grips.

Limitations of this Evidence Brief

This evidence brief sought to investigate whether processing reusable cartridge grips with low- or intermediate-level disinfection was associated with a risk of infection. This report is not a comprehensive review of the literature, but rather a rapid assessment of the available evidence. There may be relevant pieces of research not included and these may alter the conclusions drawn from the document. Overall, there was a lack of peer-reviewed literature directly related to the research question. However, because blood-borne infections often go undetected for prolonged periods of time, the lack of documented outbreaks does not rule out the potential for undetected transmission. Differences in provincial guidelines and classification also vary, and this may create challenges in estimating the risks for infection, based on differences in operator practice and routine use. Given the increased use of cartridge based tattoo machines, more research in this area may better inform both public health policy and health unit recommendations.

Implications for Practice

Given the variability in cartridges that are available, the default best practice remains to sterilize multi-use cartridge grips or use single-use disposable options. Where the public health inspector is satisfied that the needle cartridge is effectively sealed by a membrane, cartridge grips can be classified as non-critical. When this option is used, operators should ensure that the exterior of the cartridge grip is wrapped in a manner consistent with the manufacturer's instructions for use as communicated in user manuals or instructional videos. The use of disposable grip covers should not exempt them from this recommendation. Given the documented risk of mycobacteria contaminated ink, operators should use a disinfectant with a kill claim against mycobacteria when disinfecting the tattoo machine.⁵⁰

Options for assessing the efficacy of the membrane in a needle cartridge include:

- Requesting documentation from the manufacturer.
- Checking the label to ensure that the cartridge has a membrane.
- Filling one cartridge sample with fluid (e.g., tattoo ink) and operating the back-end plunger while the tip is in upright position for at least 50 times to look for signs of leakage through the plunger.

Performing a test on a cartridge involves the handling of a sharp. Sharps pose a risk of occupational injury. If this test is performed by health unit staff, they should be educated on the risks and all relevant occupational health and safety policies, procedures, and legislation.⁵¹

Only cartridges that are sealed to prevent the ingress of fluids into the machine body should be used. Tattoo machines are commonly not able to withstand an autoclave or immersion in liquid disinfectants. The use cartridges that do not have any backflow prevention may result in cross contamination and damage to the machine. Operators should contact their devices manufacturer for device specific guidance related to the cleaning and disinfection of the drive bar and other internal components in the event that a cartridge without a properly functioning membrane is used.

In instances where public health inspectors are unable to thoroughly assess the cartridges in use (e.g., tradeshow and special events), public health units may consider restricting operators to the use of single-use disposable cartridge grips.

Tattoo artists should use needle cartridges that retract the needle when not in use. Blood-borne infections remain an occupational hazard for tattoo artists and reducing their risk of exposure to blood-borne pathogens by preventing needlestick injuries is advised.

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