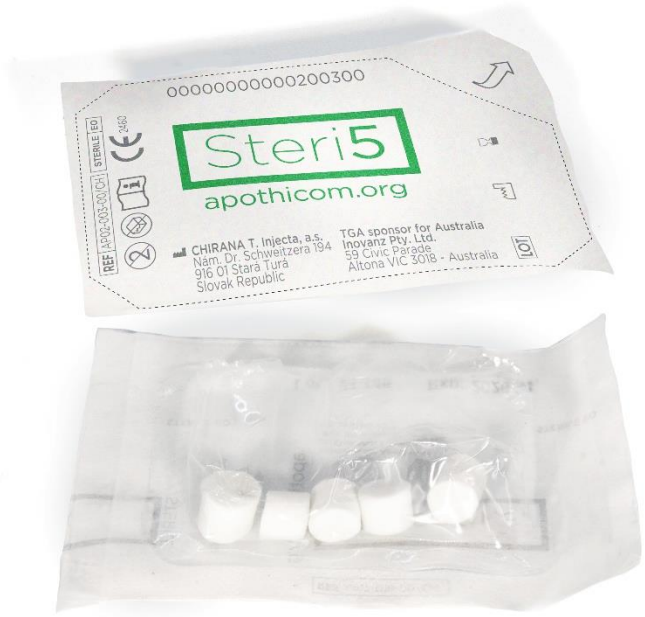
Steri5

STERILE COTTON FILTERS FOR PEOPLE WHO INJECT DRUGS



Apothicom

Tools for harm reduction
Des outils pour la réduction des risques

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1. Injection Drug Use

People who inject drugs (PWID) are persons who use substances or mixes of substances (drugs or pharmaceuticals) and who administer them by injection, usually intravenously. It is estimated that there are 15.6 million PWID worldwide (Degendhart et al., 2017), 171,900 in Canada, of which 76,700 in Ontario (Jacka et al., 2020).

Injection drug use is associated with many health problems that represent a significant source of morbidity and mortality among PWID. Beyond the risk of viral transmission (HIV and HCV in particular) associated with unsafe injection practices and sharing of injection paraphernalia, many other complications such as infections and vascular issues involving insoluble particles can be caused by this mode of administration (Del Guidice, 2004, Pieper et al., 2007).

2. Filtration of substances and associated risks

When preparing the substance to inject, PWID may use filters to remove insoluble particles from the preparation to inject in order to prevent certain complications, vein damage and to reduce the risks of needle clogging during the injection (Scott, 2008).

a) Makeshift filters

When sterile filters are not available, PWID use “makeshift” filters, among which the following are the most used (Scott, 2002 ; Scott, 2008):

- Cigarette filters
- Rolling cigarette filters (Rizla®, RAW®, …)
- Piece of cotton (removed from a cotton bud, cotton balls, …)

Not only these filters are not suitable to this use but also none of them is sterile. The necessary handling of the filter (with the fingers or the mouth) before use is associated with a risk of bacterial or fungal contamination (Gambotti et al., 2006, Scott, 2008). It is also demonstrated that removing the filter from a cigarette with the mouth is associated with a risk of candidiasis, a potentially severe fungal infection (Gambotti et al., 2006).

b) Risk of reuse and/or sharing

Filters are very often reused and/or shared (Hagan et al., 2010 ; Needle et al., 1998 ; Scott, 2008). This can be due to the lack of availability of filters but also to the residual retention of liquid inside filters (Bourgeois and Shonberg, 2009, Keijzer et al., 2010, Scott, 2008). For example, a cigarette filter retains 0.13 ml of liquid, which corresponds to 18.6% of a heroin injection of 0.7 ml (Scott, 2008).

Furthermore, because of the necessary contact between the filter and the syringe or needle during the filtration, used filters become vectors of viral transmission (HIV, HCV).

c) Risk of viral transmission

In laboratory, the presence of HIV was detected on used filters (Shah et al., 1996) as well as VHC (Crofts et al., 2000). On the field, it has been demonstrated that HIV-positive persons are more likely to have shared their filters than HIV-negative persons (Vlahov et al., 1997). A correlation between the sharing of equipment (cookers, water and filters) and the transmission of HIV was found (McCoy et al., 1998), and lastly, the sharing of filters is a strong indicator for seroconversion of HCV (Bruandet et al., 2006, Hagan et al., 2010, Thorpe et al., 2002).

d) Risks related to the injection of insoluble particles

Many health complications that are related to injection drug use are caused by the injection of insoluble particles into the blood stream. These insoluble particles, such as starch, talc or magnesium stearate, may be cutting agents that are added to illicit drugs (Cole et al., 2010) or pharmaceutical excipients such as binders that are present in drugs that are not intended for intravenous injection (Hind, 1990). Most of pharmaceutical drugs that are diverted to be injected are formulated for oral administration and may therefore contain large amounts of insoluble excipients. Most of insoluble particles will indefinitely persist in the body once they have been injected.

Several complications, ranging from mild to severe, are associated with the injection of such foreign bodies. At the injection site, they can cause sterile abscesses, cellulitis and ulcers (Del Guidice, 2004, Hahn et al., 1969).

Insoluble particles (such as talc), once in the bloodstream, remain solid and can therefore obstruct the blood flow in narrow blood vessels like pulmonary capillaries, which diameter can be less than 10 µm (Kaga et al., 1982). Repeated administrations and long-term injection drug use may consequently cause pulmonary and cardiac complications such as pulmonary embolism, respiratory failure, fibrosis, cardiac failure and pulmonary talcosis (Lamb and Robert, 1972, Sieniewicz and Nidecker, 1980, Paré et al., 1998). Furthermore, the consequences of their injection on veins can be severe as they can cause vein irritation, thrombosis, phlebitis and vein damage (Padilla et al., 1979).

The size distribution of most insoluble particles that are involved in the development of health complications is 9 µm to 23 µm, with an average size of 14 µm (Abraham and Brambilla, 1980). When particles pass the pulmonary barrier, they tend to disseminate in the body and can be found in eyes, brain, kidneys or liver (Paré et al., 1979, Rumbaugh et al., 1971, Hahn et al., 1969, Kringsholm and Christoffersen, 1987).

Poor filtration has been identified as one of the risk factors for the development of these complications (Jampol et al., 1981).

e) Risks of bacterial and fungal infections related to the injection of insoluble particles

Skin and soft-tissue infections (SSTIs) are common in PWID. For example, it is estimated that between 6.1% and 32.0% of PWID had an abscess during the last month (Larney et al., 2017). The injection of insoluble particles is an important factor of infectious risk: the development of an infection is indeed more frequent and the infection is more intense when particles are injected concomitantly. This is due to the direct action of insoluble particles that cause lesions where bacteria that have been introduced into the body during the injection can settle and multiply (Staikowsky et al., 1998). Abscesses, cellulitis, endocarditis and septicaemia may be the consequence of their development (Del Guidice, 2004).

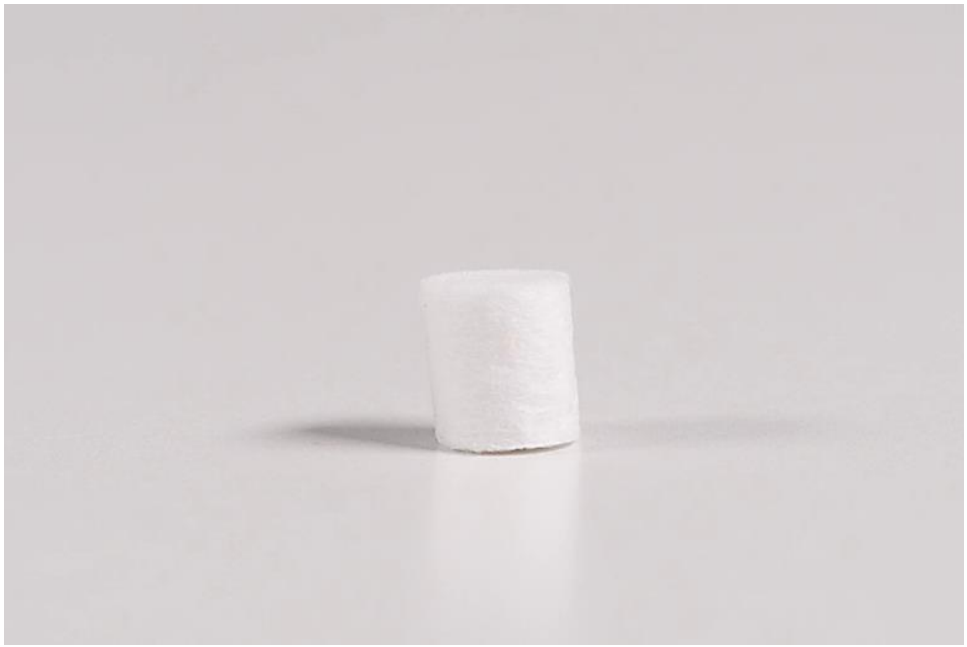
The number of insoluble particles in pharmaceuticals is higher than in most “illicit” drugs. Their injection is therefore associated with a higher risk of complications (Hopkins and Taylor, 1970; Sieniewicz and Nidecker, 1980; McLean et al., 2017) and skin and soft tissue infections (Cadet-Taïrou et al., 2008, Dwyer et al., 2009).

3. Steri5: Sterile cotton filters

As authors well documented the risks of using makeshift filters as well as their potential role in viral transmission and other infections in PWID, the first filters dedicated to this use were designed, including Apothicom sterile filters, offered since 1997.

Characteristics:

- Dimensions: 6 mm x 6 mm
- Material: 100% hydrophilic cotton



a) Benefits of sterile cotton filters

The adoption of injection supplies offered to PWID is essential for needle exchange programs and other harm reduction programs to involve them in safer practices and the adoption conditions the use of these supplies. In France, Apothicom sterile cotton filter is used by more than 50% of PWID (Jauffret-Roustide et al., 2017) and this suggests that this filter is not only acceptable but also adopted by PWID.

Its acceptability, combined with its affordability and thus accessibility, allow an extensive distribution of sterile cotton filters.

Some authors (Aspinall et al., 2012) demonstrated that the distribution of sterile cotton filters in harm reduction programs decreases sharing and thus reduces viral infectious risks. Because it is sterile, it also reduces bacterial and fungal infectious risks (Scott, 2008).

The availability of single-use sterile cotton filters contributes to the promotion of safer injection practices and personal use of injection supplies. By removing more insoluble particles than “makeshift” filters such as cigarette filters, cotton filters reduce risks associated with the injection of insoluble particles (Scott, 2002; Scott, 2008).

b) Risk-benefit profile of sterile cotton filters

The assessment of the risk-benefit profile of sterile cotton filters is important to answer the following questions:

- Is it better to distribute sterile cotton filters than no filters?
- Why is the sterile cotton filter still distributed while more effective filters exist?

Because these filters are made of cotton, fibers could be released in the liquid preparation by the filter itself and possibly cause complications comparable to the ones associated with the injection of solid particles found in such preparations without filtration.

This risk is however considered as acceptable for the following reasons:

- More than 100 million filters have been distributed in many countries and it has never been related to health issues observed in cotton filter users.
- Some PWID will not use other filters than cotton ones, even if they have access to more effective filters such as membrane filters. Some of them consider that it would take too long to use them (Keijzer and Imbert, 2011), that they are not easy to use or merely that they don’t want to use a different filter. If the cotton filter was not available, they would instead use “makeshift” filters rather than more effective filters. As explained in “Best Practice Recommendations” (Strike et al., 2013), it is central to offer supplies that PWID want to use and that are well accepted.
- Infectious risks (bacterial and fungal) are associated with “makeshift” filters, as described in section 2.a. Because it is sterile and does not need to be handled with hands or mouth before use, the cotton filter is associated with lower infectious risks.

Sterile cotton filters are also more effective than "makeshift" filters to remove insoluble particles (see table below) (Scott, 2002).

Important:

- "Cigarette": cigarette filters
- "Cotton": pieces of cotton from cotton-buds
- "Dental": Apothicom sterile cotton filter

Table 4: The effect of filtration on the number of particles in an injection made with half of a Subutex 8mg tablet.

Filter	Ave. no. particles counted in 12 s after filtration (see fig.3)*	Percentage reduction in no. of particles compared to unfiltered (see fig.4)	RSD of five counts (%)
None (spoon)	13418	-	12
None (using Steribox kit)	11974	11	41
Cigarette	10413	22.	15
Rizla	8442	37	41
Cotton	5915	56	72
Dental	1363	90	22

RSD = (standard deviation / mean) x 100

**Please note this does not mean the average number of particles in the injection. A standard method was used allowing samples to be compared. This is the number of particles counted in 12 seconds when a 50 microlitre sample of injection is added to 75ml of Isoton analysis fluid.*

Source: J. Scott, 2002

Finally, the risk-benefit profile of the sterile cotton filter is ensured by its filtration efficacy. PWID inject substances, illicit drugs or diverted medications than contain high amounts of insoluble particles. During the development phases of membrane filters, Apothicom conducted many filtration tests and the cotton filter was also part of tested filters. Particles larger than 10 µm being the most harmful, their count was the most critical data to consider. These tests supported results obtained by Scott.

		No. of particles counted (in 2.0 ml)	
		Particles > 10 µm	Particles > 25 µm
Ritaline (Methylphenidate, 10 mg tablet)	No filter	5 837 198	1 425 908
	Sterile cotton filter	14 462	196
	% of reduction	99.75 %	99.99 %
Skénan (Morphine sulfate, 100 mg, capsules, heated)	No filter	4 547 674	182 220
	Sterile cotton filter	243 690	2 668
	% of reduction	94.60 %	98.50 %
Subutex (Buprenorphine, 8 mg tablet)	No filter	8 149 598	865 192
	Sterile cotton filter	1 704 226	11 040
	% of reduction	79.09 %	98.72 %

Source: Apothicom

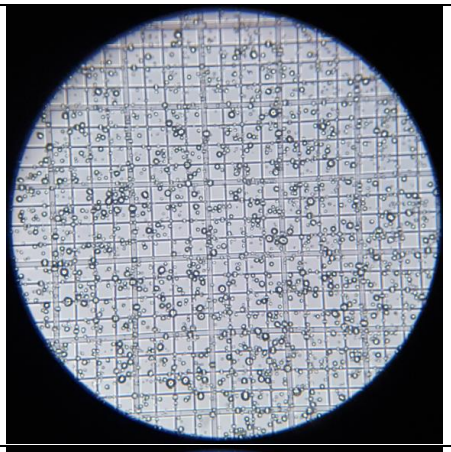
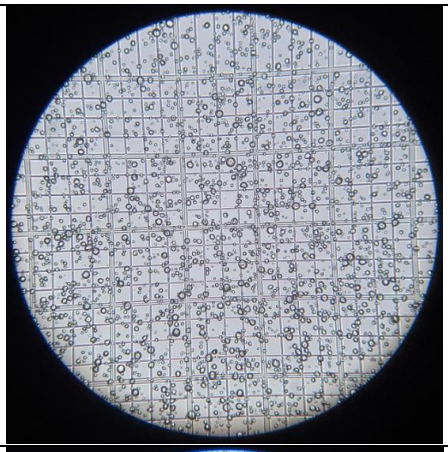
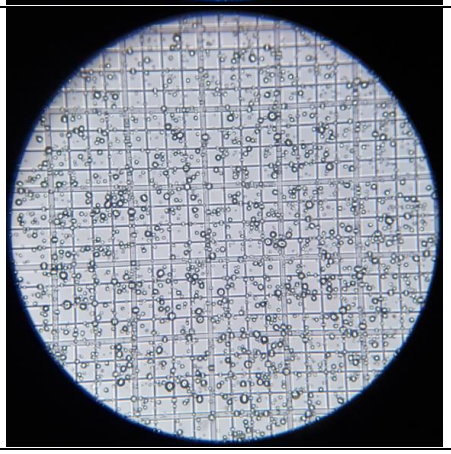
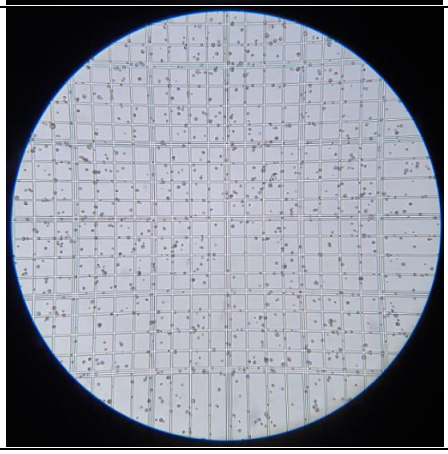
Insoluble particles released by the cotton filter were also counted in 2 ml of water before and after filtering with a sterile cotton filter: 13 particles > 10 µm and 0 particle > 25 µm were released.

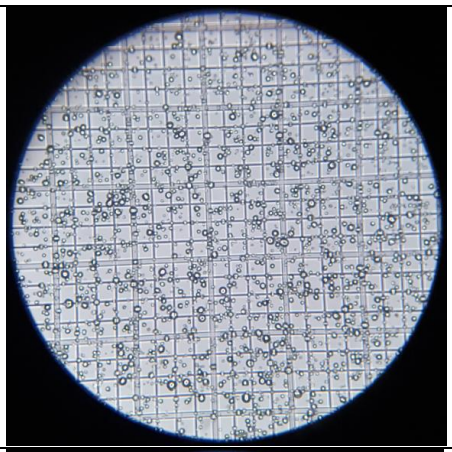
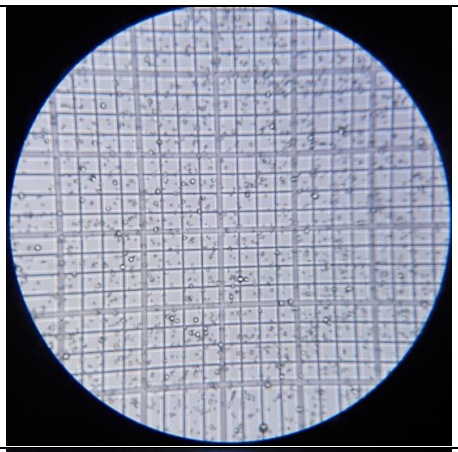
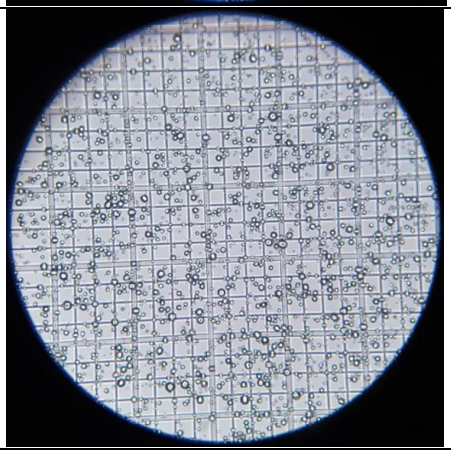
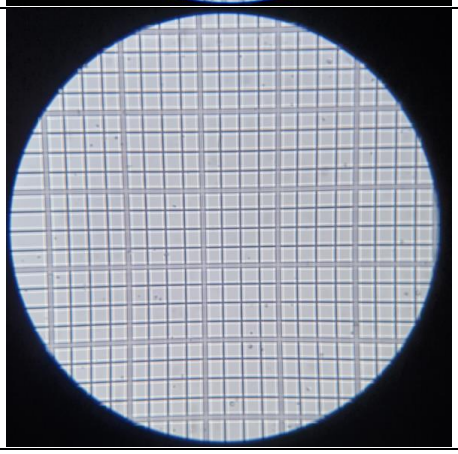
The amount of particles released by the cotton filter is therefore insignificant in comparison with the proportion of particles (> 10 µm) removed by it, which is between 79.09% and 99.75%, according to what is filtered.

c) Before and after filtration photographs

Filtration tests were performed with different filters and photographed (Neubauer counting chamber, 50 µm grid, 75 ml of water and 1.50 g of starch, which particles size range is comparable to drugs):

- Cigarette filter (7 mm x 5.2 mm)
- Living Stone non-sterile cotton roll (piece of 7 mm)
- Cellulose acetate filter (8 mm)
- Apothicom sterile cotton filter (6 mm)

Filter	Before filtration	After filtration	Syringe content after filtration
Cigarette filter			
Living Stone cotton roll			

Cellulose acetate filter			
Apothicom cotton filter			

Source: Apothicom

4. Conclusion

More effective filters than cotton filters exist, for example, membrane filters that are equipped with filtering membrane of 10 µm or even 0.22 µm (antibacterial). However, the cotton filter remains a valuable and effective alternative to the use "makeshift" filters. Membrane filters to be properly adopted, call for appropriate education and their use can be challenging for some people. Affordability also remains a key criterion of sterile cotton filters high accessibility in many countries.

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