



High Quality
Pipette Tips
for Consistent
and Reliable Results

Simplifying Progress

SARTORIUS

Excellence in Quality and Convenience

Sartorius pipette tips ensure the performance of Sartorius pipettes and repeatability of your results like no other tip can. They have been designed and manufactured to meet the highest quality and purity standards and to be the inert protectors of your samples. Moreover, correctly fitting tips protect the pipette's tip cone from wear and tear.

Sartorius tip packages are designed to make the daily work of lab professionals easier. Our offering covers a variety of functional tip package options with various purity ratings.

The high purity and consistent quality of Sartorius tips provide your valuable samples with the ultimate protection from contamination. We adhere to strict quality standards and control procedures – from raw material to automated manufacturing and packaging.

Pure Quality

- Tips are manufactured using a fully automated process in ISO class 8 cleanroom conditions to ensure purity
- Strict standards, followed from R&D to production and delivery: ISO 9001, ISO 140001, and ISO 13485
- Every batch of purity certified tips is tested and verified as free of DNase, RNase, human DNA and endotoxins
- Using Sartorius tips with Sartorius pipettes guarantees perfect tip sealing, ensuring reliable results with high precision and accuracy
- Tip-purity certificates can be easily downloaded from our website, www.sartorius.com
- Tips are manufactured using virgin polypropylene without any additives





Convenient

- Smart color codes make it quick and easy to find the right tip for your pipette
- Versatile package options are available for various needs
- Sartorius pipettes feature Optiload® and Optiject® functions for smooth tip attachment and ejection
- Pre-sterilized tips are available for demanding applications
- Compatible with most pipette brands

Fully Compliant

- Every tip package is clearly marked with the volume, color code, purity grade, expiry date, product code, and lot number
- The lot number enables full traceability right from production

High Quality Tips for Various Pipetting Applications

Optifit Tips – Standard Multipurpose Tips for Various Applications

Optifit Tips are high-quality standard tips and an excellent solution for various applications. Non-filter Optifit Tips are available in various purity levels and package options. Optifit Tips are also fully autoclavable at 121°C for 20 minutes with 1 bar /100 kPa pressure.

Optifit Tip Range

- Extended and wide-bore tips for specific applications
- Pre-sterilized and non-sterile
- Purity certified Single Tray racks and Refill Packs
- Single Tray racks, Refill Packs, Refill Towers and Bulk packages
- Volume range from 10 µL to 10 mL

Safetyspace™ Filter Tips – Filter Tips for Contamination Protection

Safetyspace™ Filter Tips offer optimal protection for your work from cross contamination and enable you to use the full volume of the tip with any pipetting mode. They feature the unique Safetyspace™ air gap that leaves additional space between the sample and the filter that conventional filter tips do not have. This extra space prevents the liquid from touching, and permeating, the filter and thus guarantees the pipetting accuracy.

Safetyspace™ Filter Tips provide protection from contamination for pipettes and samples in the following applications:

- molecular biology
- microbiology
- cell culture
- radioactive work

Safetyspace™ Filter Tip Range

- Pre-sterilized
- Purity certified
- Single Tray racks
- Volume range from 10 to 5,000 µL



Low Retention Tips – Hydrophobic Tips for Maximum Sample Recovery



The four Low Retention Tips on the right retain the minimum amount of residual liquid.

Low Retention Tips maximize sample recovery and the accuracy of results when pipetting detergent containing solutions or other liquids with low surface tension. Using patented Sartorius technology, we can manufacture tips with fully hydrophobic and highly liquid-repellent surfaces. Low Retention Tips offer excellent chemical resistance without any leachables.

Low Retention Tips are beneficial in sensitive molecular biology applications, where reagents often contain viscous substances and detergents. These applications can include:

- PCR and real-time PCR
- cloning, sequencing, and other DNA & RNA techniques
- SDS-PAGE and other protein analysis methods
- protein purification techniques

Low Retention Tip Range

- Available as Safetyspace™ Filter tips and Optifit tips
- Pre-sterilized and non-sterile
- Single Tray racks and Refill Towers
- Volume range from 10 to 1,200 µL

Unique Safetyspace™ Feature



Safetyspace™ – the additional space between the sample and filter.

Low Retention Tips maximize sample recovery and the Safetyspace™ Filter Tips have additional space between the sample and filter. Any liquid types and pipetting techniques can be applied without the risk of the liquid permeating the filter.

The extra space is particularly beneficial in the following applications:

- pipetting foaming liquids such as buffers and proteins
- when using electronic pipettes with multiple dispensing functions
- reverse pipetting

A Convenient Range of Package Options

Sartorius tip packages are designed to make the daily work of lab professionals easier. Our offering covers a variety of functional tip packages with various purity ratings.

Smart color codes make it quick and easy to find exactly the right tip for your pipette. The trays, racks, and non-filter tips are fully autoclavable at 121°C, 20 minutes, 1 bar/100 kPa. All tips, trays, and racks are made of 100 % pure polypropylene and are recyclable as energy waste.

Single Tray Racks



- 96 tips in convenient and reusable tray racks
- Each batch is certified free of DNase, RNase, human DNA and endotoxins
- Informative rack labelling enables easy tip identification and traceability
- Hermetically sealed plastic wrapping ensures purity
- Empty racks can be easily reloaded with tips from Refill Towers and Packs

Refill Packs

The fast and easy way to refill empty Single Tray racks.



Refill Tower

- Reuse and reload empty racks easily
- Save space: 10 × 96 tips in each tower
- Available in the most widely used tip sizes: 10 µL, 200 µL, and 350 µL
- 100 % recyclable cardboard package



Refill Packs

- Reuse and reload empty racks easily
- Each batch is certified free of DNase, RNase, human DNA and endotoxins
- Individually packed hermetically sealed tip trays for maximum purity
- Pre-sterilized option available



Bulk Packs

Bulk packages of high-quality tips



FlexiBulk®





- Fast and convenient reloading of racks due to orderly packed tips.
- Compact and airtight resealable plastic package
- Each batch is certified free of DNase, RNase, human DNA and endotoxins

Bulk in a Box





- Economical resealable bag of tips in cardboard packaging
- Available in 10 µL, 5 mL, and 10 mL

Ordering Information

Optifit Tips

Volume Range	Length	Packaging	Low Retention	Purity Level		Tips/Unit	Order Code
				Free of DNase, RNase, human DNA & endotoxins	Pre-sterilized		
<div><div></div><div>0.1–10 µL</div></div> <div></div>	31.5 mm	Single Tray	■	■		10×96	790010
		Single Tray		■		10×96	LH-L790010
		Single Tray		■	■	10×96	790011
		Refill Tower	■			10×96	790012
		Refill Tower				10×96	LH-L790012
		Refill Pack		■	■	20×96	790013
		Bulk in Bag				1,000	790014
<div><div></div><div>0.5–200 µL</div></div> <div></div>	51 mm	Single Tray	■	■		10×96	790200
		Single Tray		■		10×96	LH-L790200
		Single Tray		■	■	10×96	790201
		Refill Tower	■			10×96	790202
		Refill Tower				10×96	LH-L790202
		Refill Pack		■	■	15×96	790203
		FlexiBulk®		■		960	LH-B790204
<div><div></div><div>5–350 µL</div></div> <div></div>	54 mm	Single Tray	■	■		10×96	790350
		Single Tray		■		10×96	LH-L790350
		Single Tray		■	■	10×96	790351
		Refill Tower	■			10×96	790352
		Refill Tower				10×96	LH-L790352
		Refill Pack		■	■	15×96	790353
		FlexiBulk®		■		960	LH-B790354
<div><div></div><div>10–1,000 µL</div></div> <div></div>	71.5 mm	Single Tray	■	■		10×96	791000
		Single Tray		■		10×96	LH-L791000
		Single Tray		■	■	10×96	791001
		Refill Pack	■	■		10×96	791002
		Refill Pack		■	■	10×96	791003
		Refill Pack		■		10×96	LH-B791004
		FlexiBulk®		■		480	









For your guidance the tips are shown here in the actual size.

Volume Range	Length	Packaging	Low Retention	Purity Level		Tips/Unit	Order Code
				Free of DNase, RNase, human DNA & endotoxins	Pre-sterilized		
<div></div> 10 – 1,000 µL Wide bore tip	68.5 mm	Single Tray Single Tray FlexiBulk®		<div></div> <div></div> <div></div>	<div></div>	10 × 96 10 × 96 480	791020 791021 LH-B791024
							
<div></div> 50 – 1,200 µL	71.5 mm	Single Tray Single Tray Single Tray Refill Pack Refill Pack FlexiBulk®	<div></div>	<div></div> <div></div> <div></div> <div></div> <div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96 10 × 96 10 × 96 10 × 96 480	791200 LH-L791200 791201 791202 791203 LH-B791204
							
<div></div> 100 – 5,000 µL	150 mm	Single Tray Single Tray Bulk in Bag Bulk in Bag		<div></div> <div></div>	<div></div>	50 50 100 1,000	780304 780305 780300 780308
							
<div></div> 100 – 10,000 µL	155 mm	Single Tray Bulk in Bag				35 250	LH-780314 LH-780316
							

Note: The ordering information for 10,000 µL tip for Midi Plus can be found on page 69.









Ordering Information

Safetyspace™ Filter Tips






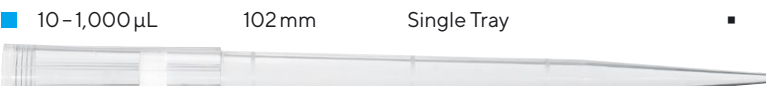
Volume Range	Length	Packaging	Low Retention	Purity Level		Tips/Unit	Order Code
				Free of DNase, RNase, human DNA & endotoxins	Pre-sterilized		
<div><div></div>0.1–10 µL</div> <div></div>	31.5 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	790011F LH-LF790011
<div><div></div>0.5–20 µL</div> <div></div>	51 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	790021F LH-LF790021
<div><div></div>2–120 µL</div> <div></div>	51 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	790101F LH-LF790101
<div><div></div>0.5–200 µL</div> <div></div>	52.5 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	790201F LH-LF790201
<div><div></div>0.5–300 µL</div> <div></div>	52.5 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	790301F LH-LF790301
<div><div></div>50–1,000 µL</div> <div></div>	78 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	791001F LH-LF791001
<div><div></div>50–1,200 µL</div> <div></div>	90 mm	Single Tray Single Tray	<div></div>	<div></div> <div></div>	<div></div> <div></div>	10 × 96 10 × 96	791211F LH-LF791211
<div><div></div>100–5,000 µL</div> <div></div>	150 mm	Single Tray		<div></div>	<div></div>	50	LH-795001F

For your guidance the tips are shown here in the actual size.
Filter tips are not recommended to be used simultaneously with Safe-Cone Filters.

Extended Standard Tips

Volume Range	Length	Packaging	Low Retention	Purity Level		Tips/Unit	Order Code
				Free of DNase, RNase, human DNA & endotoxins	Pre-sterilized		
 0.1–10 µL	46 mm	Single Tray		■		10 × 96	783210
		Single Tray		■	■	10 × 96	783211
 0.5–200 µL	77.5 mm	Single Tray		■		10 × 96	LH-X780200
		Single Tray		■	■	10 × 96	LH-X780201
 10–1,000 µL	102 mm	Single Tray		■		8 × 96	LH-X781000
		Single Tray		■	■	8 × 96	LH-X781001
 50–1,200 µL	90 mm	Single Tray	■	■		10 × 96	791210
		Single Tray		■		10 × 96	LH-L791210
		Single Tray		■	■	10 × 96	791211
		Refill Pack		■		10 × 96	791212
		Refill Pack		■	■	10 × 96	791213
							

Extended Filter Tips

 0.1–10 µL	46 mm	Single Tray		■	■	10 × 96	783201
 0.5–200 µL	77.5 mm	Single Tray		■	■	10 × 96	LH-XF780201
 10–1,000 µL	102 mm	Single Tray		■	■	8 × 96	LH-XF781001

For your guidance the tips are shown here in the actual size.
Extended filter tips are not recommended to be used simultaneously with Safe-Cone Filters.
The liquid handling properties of extended tips might differ from standard Optifit tips.

Protect Your Pipette and Sample with Safe-Cone Filters

Safe-Cone Filters act as a final barrier to prevent any fluids and liquid vapors from coming into contact with the internal components of the pipette. These unique and replaceable filters are made of polyethylene (PE). They:

- protect the pipette and sample from contamination
- prolong the pipette's lifetime
- reduce maintenance intervals

Safe-Cone Filters cannot be used together with filter tips.

Plus Filter

For more demanding applications such as radioactive work, cell culture, bacterial and virological work, and molecular biology.

Standard Filter

For general applications. These filters can be used for the same applications as the Plus filter, but need to be changed more frequently.



Removing the Safe-Cone Filter

Safe-Cone Filters

Order Code	Item	Qty/Unit
721008	Standard Ø 2,51 mm PE	50
721007	Standard Ø 3,15 mm PE	50
721006	Standard Ø 5,33 mm PE	50
721005	Standard Ø 6,73 mm PE	50
721014	Standard Ø 1,83 mm Polyolefin	50
721018	Plus Ø 2,51 mm PE	50
721017	Plus Ø 3,15 mm PE	50
721016	Plus Ø 5,33 mm PE	50
721015	Plus Ø 6,73 mm PE	50

PE = polyethylene



Responsible Manufacturing

At Sartorius, we understand our responsibility as a single-use plastic consumable manufacturer. This is why we pay particular attention to the environmental impact of our operations and products, throughout their lifecycle: from product design, packaging, and all the way through to our production technology.

Environmentally Friendly Design

Beginning at the design stage, we look for ways of reducing the number of plastics and hazardous substances and materials we use. In our approach, we also look at the production process, energy and waste streams, and all the way to our office spaces. Let's look at how the design of the various packaging options can help you choose the best options for your lab:

The single tray pipette tip boxes are intended for applications requiring the utmost purity of products and are designed to have a small plastic footprint (Fig 1.).

- The refill packages, in contrast, are designed to give the option for a reduced plastic footprint, while also maintaining product purity. When you choose the refill packages, the amount of plastic saved per package is the equivalent of approximately 38 water bottles per package compared to the single tray box (Fig 2.).
- The refill tower system is an ecological yet practical option that reduces the total waste of all product packaging by up to 61% and plastic by up to 48% compared to single tray box tips. Thanks to the small footprint of the product, when you choose this option, you also help reduce transportation emissions, as the package is only one-third the size of the single tray package, yet it contains the same number of pipette tips.
- Finally, the FlexiBulk tip pack is the most ecological and economical choice; this package uses up to 67% less plastic and weighs 30% less compared to the single tray option. The amount of plastic saved per package is comparable to 75 water bottles and the package itself is less than half the size of the single tray package, which further reduces emissions from shipping.

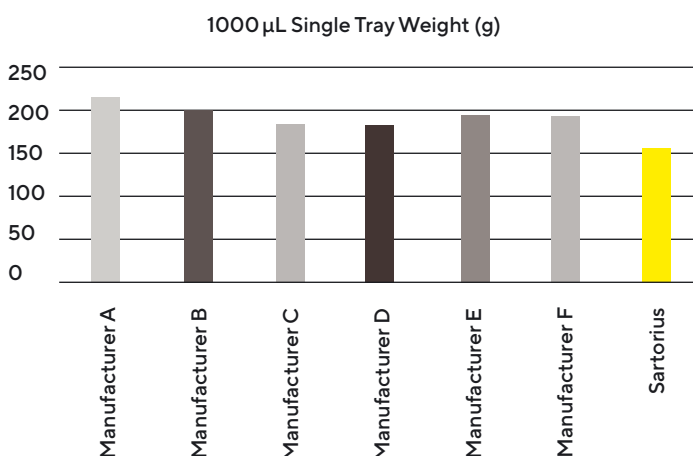


Figure 1. Amount of plastic in single tray boxes of several single-use pipette tip manufacturers. Sartorius's single tray tip box is designed to use the least amount of plastic possible, while also providing a stable box from which to pick pipette tips.

Note: the average 0.5 L water bottle weighs 10 g.

Environmentally Friendly Manufacturing

At our manufacturing sites, we have invested in production technologies that generate less waste. Our pipette tip production facility in Kajaani, Finland uses 100 % renewable electricity and has achieved a waste recovery rate of 98 %. Additionally, plastic waste from Sartorius pipette tip manufacturing is recycled for use as raw materials for other plastic products. We are continuously working to reduce our environmental impact, and to drive this, Sartorius Biohit Liquid Handling complies with ISO 14001 environmental standards.

Recyclable Materials

The plastic material used in the products and their packaging is suitable for recycling or use in waste-to-energy facilities (Fig 3.). For example, tips and tip racks made of 100 % polypropylene (PP) can be fully recycled as energy waste. The cardboard packages are made from recycled material and are fully recyclable.



Figure 2. Reduced weight of total plastic material per 960 tips when compared to single tray package. Comparison performed using 350 µL Optifit Tip products.

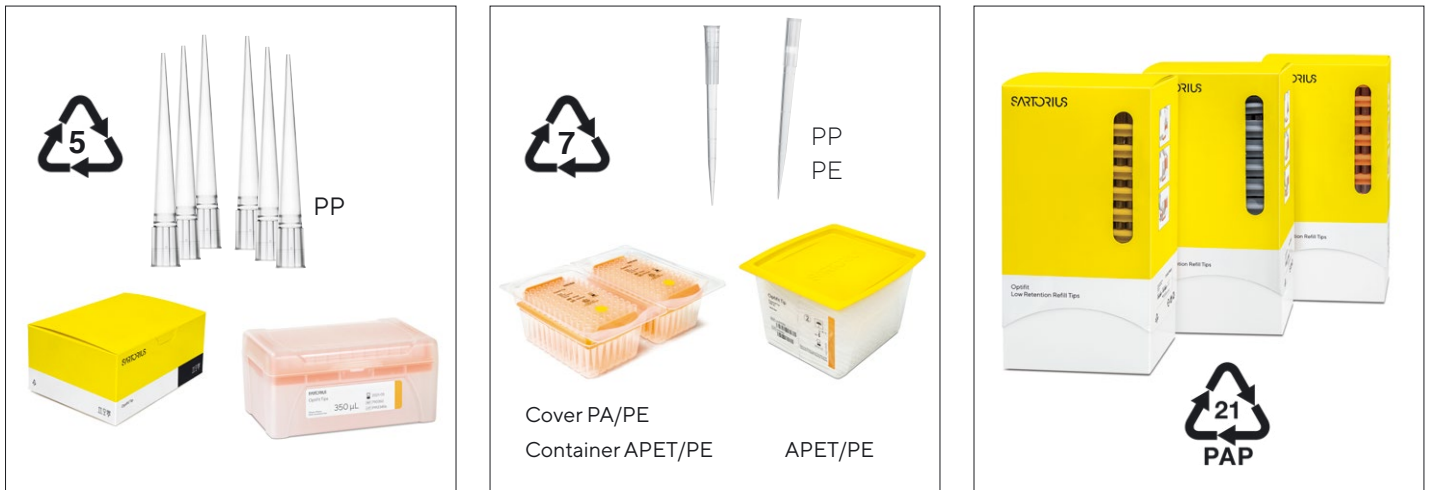


Figure 3. The plastic material used in the products and their packaging is suitable for recycling or use in waste-to-energy facilities. For example, tips and tip racks made of 100 % polypropylene (PP) can be fully recycled as energy waste. The product box, tray, and air-tight wrapping are made of polypropylene. Also, used Optifit tips can be recycled, if used to pipette non-hazardous materials. Sales unit packages and refill tower packages are made from recyclable cardboard. The FlexiBulk and refill package material are mixed plastic; therefore, follow local guidelines for recycling. Resin identification codes (RIC) defined by the European Commission.

Summary

100 % renewable energy used by manufacturing sites in Finland	Waste heat rerouted to heat the manufacturing sites in Finland	WEEE ROHS compliant electronic pipettes
100 % recyclable or combustible pipette tips, trays and boxes	Outer packaging from recycled cardboard	90 % recyclable mechanical pipettes
ISO 14001 Environmental management certified	98 % of waste recycled at manufacturing sites in Finland	Sartorius is a Signee of the European Plastics Pact

Sartorius Design and R&D – The Driving Force Behind Our High-Quality Products

Customer needs are always the starting point when developing and manufacturing Sartorius pipettes and pipette tips. As our customers have their own unique preferences and because pipetting needs vary between applications and users, we provide our customers with liquid handling equipment that matches their applications precisely and fulfills even the strictest quality standards. Ergonomics, performance, and reliability are the cornerstones of our design and product development processes. Strong technical innovation and the latest design and manufacturing technologies ensure the high quality and performance of our products.

Sartorius has a rich and extensive history in liquid handling. Our experience and knowledge of pipette and pipette tip design has resulted in several award-winning innovations and products. The Sartorius liquid handling competence center masters the entire value chain, from customer needs

and product design to manufacturing. Our in-house R&D capabilities with experienced liquid handling experts enable continuous product and process development and the creation of new, innovative solutions. Designing Sartorius tips goes beyond mere tip geometry: our R&D team also designs the tip molds in order to ensure the highest possible quality and consistency.

Sartorius has modern production facilities for pipettes and tips. Our highly automated tip manufacturing facility allows us to maintain the highest quality and purity standards by selecting the best plastic materials and controlling the manufacturing process from beginning to end. Our quality management system follows not only ISO 9001 and ISO 14001, but also ISO 13485. Tip production also complies with the ISO 14644-1 standard, in order to fulfill ISO Class 8 cleanroom conditions for guaranteed tip purity.





















































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winner

Ensure the Highest Pipetting Performance and Precision

Sartorius tips are designed and manufactured to perfectly fit with Sartorius pipettes enabling maximum tip sealing and accuracy.

Pipette Tip Selection Guide

			Picus® and Picus® NxT									
Electronic Pipettes			1-ch						8 & 12-ch			
	Color Code	µL	0.2 – 10	5 – 120	10 – 300	50 – 1,000	100 – 5,000	500 – 10,000	0.2 – 10	5 – 120	10 – 300	50 – 1,200
Optifit Tips		0.1 – 10										
		0.1 – 10 Ext.										
		0.5 – 200										
		0.5 – 200 Ext.										
		5 – 350										
		10 – 1,000										
		10 – 1,000 Ext.										
		10 – 1,000 WB										
		50 – 1,200										
		50 – 1,200 Ext.										
		100 – 5,000										
		1 – 10 mL										
Safetyspace™ Filter Tips		0.1 – 10										
		0.1 – 10 Ext.*										
		0.5 – 20										
		2 – 120										
		5 – 200										
		0.5 – 200 Ext.										
		5 – 300										
		50 – 1,000										
		50 – 1,000 Ext										
		50 – 1,200										
		100 – 5,000										

Note: Low Retention Tips are available in volumes up to 1,200 µL.

* Filter tip with standard air gap. In tests, 10 µL extended tip's systematic error and random error results, deviated slightly from those of the 10 µL tip.

Ensure the Highest Pipetting Performance and Precision

Sartorius tips are designed and manufactured to perfectly fit with Sartorius pipettes enabling maximum tip sealing and accuracy.

Pipette Tip Selection Guide

Tacta® and mLINE®													Proline® Plus																				
1-ch													8 & 12-ch				1-ch													8 & 12-ch			
	Color Code	μL	0.1-3	0.5-10	2-20	10-100	20-200	100-1,000	500-5,000	1-10 mL	0.5-10	5-100	30-300	0.1-3	0.5-10	2-20	5-50	10-100	20-200	100-1,000	500-5,000	1-10 mL	0.5-10	10-100	30-300								
Optifit Tips	■	0.1-10	■	■							■			■	■								■										
	■	0.1-10 Ext.	■	■							■			■	■								■										
	■	0.5-200			■	■	■				■					■	■	■	■					■									
	■	0.5-200 Ext.			■	■	■				■					■	■	■	■					■									
	■	5-350											■												■								
	■	10-1,000						■									■			■													
	■	10-1,000 Ext.						■									■			■													
	■	10-1,000 WB						■									■			■													
	■	50-1,200																															
	■	50-1,200 Ext.																															
	■	100-5,000							■												■												
	■	1-10 mL									■												■										
Safetyspace™ Filter Tips	■	0.1-10	■	■							■			■	■								■										
	■	0.1-10 Ext.*	■	■							■			■	■								■										
	■	0.5-20			■											■																	
	■	2-120				■					■						■	■						■									
	■	5-200					■												■														
	■	0.5-200 Ext.				■	■				■						■	■	■					■									
	■	5-300											■												■								
	■	50-1,000						■												■													
	■	10-1,000 Ext.						■												■													
	■	50-1,200																															
	■	100-5,000							■												■												

Note: Low Retention Tips are available in volumes up to 1,200 μL.

* Filter tip with standard air gap. In tests, 10 μL extended tip's systematic error and random error results, deviated slightly from those of the 10 μL tip.

Proline®									
1-ch								8 & 12-ch	
	0.1-2.5	0.5-10	2-20	5-50	10-100	20-200	100-1,000	1,000-5,000	
	■	■							■
	■	■							■
			■	■	■	■			■
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Ergonomic and Reliable Sartorius Pipettes

Sartorius pipettes provide the perfect solution for your liquid handling needs. Sartorius pipettes and tips fit seamlessly together and provide you with maximum pipetting performance and exact accuracy and precision. Sartorius

offers the leading range of superior electronic and mechanical pipettes. For more information, visit www.sartorius.com. Sartorius also provides pipette maintenance, repair, and calibration services globally. Contact your nearest Sartorius service center or office for more information.

Sartorius ABC of Tip Purity

Additive-free

Manufacturing tips from pure virgin polypropylene minimizes the risk of substances from the tip material leaching into samples. This is why Sartorius tips are free of colors, clarifying agents, and plasticizers.

DNase-free

DNases are powerful enzymes (nucleases) that degrade DNA by hydrolyzing it into short fragments. Even trace amounts of DNases can lead to low or no yields in DNA techniques such as PCR. DNase contamination sources are human contact and bacteria. DNase-free tips are tested for DNase activity with fluorometric assay by detecting degradation of labeled DNase substrate. DNase-free pipette tips show no evidence of DNase activity in the assay with a detection level of $<6,25 \cdot 10^{-5}$ U/ μ L when DNase I was used as a standard.

Endotoxin-free

Endotoxins are lipopolysaccharides that are part of the outer membrane of Gram-negative bacteria. They cause fever in humans and impair the growth of cell cultures. Endotoxins are very durable and are present wherever bacteria are able to grow, i.e. air, water, soil, skin, raw materials, and in any non-sterile environment. When certified endotoxin free, the tips are tested according to FDA guidelines for medical devices. The Ph. Eur. 2.6.14, Method D. Validated test result for endotoxin-free tips is $<0,005$ IU/mL (EU/mL).

Human DNA-free

Sartorius purity certified tips are analyzed for the presence of DNA using quantitative PCR and human DNA specific primers. The determined detection limit of the assay is <1 pg/ μ L.

RNase-free

RNases are enzymes that catalyze the degradation of RNA into short fragments. These very stable enzymes are difficult to remove and originate from human skin, hair, and saliva, as well as from bacteria. Tips are tested for RNase activity using fluorometric assay. RNase-free tips show no evidence of RNase activity with a detection level of $<3,125 \cdot 10^{-9}$ U/ μ L when RNase A was used as a standard.

Sterilization

The destruction of all microbial life, including bacterial endospores. Sterility can be accomplished using, for example, steam, heating, chemicals, or radiation. Sartorius pre-sterilized tips are sterilized with an electron beam (beta irradiation) in accordance with EN 552 and ISO 11137, and the process is validated by using 25 kGy as the minimum dose, with an SAL (sterility assurance level) of 10^{-6} .

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