



Pharma

Chromatography columns and consumables

# Pharma workflow solutions

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# Complete pharma workflow solutions

For pharma scientists pursuing great understanding of quality control and impurity regulation the correct workflow selection – from when the sample enters the lab until the sample is analyzed – can be imperative for their results.

We strive to create a better understanding of how to compose an optimal workflow allowing scientists to improve their method and resolve more, even save time and solvent, while staying within government regulations. The workflows in this brochure represent a fraction of available solutions from Thermo Fisher Scientific.

## Discovery DMPK

- Thermo Scientific™ HyperSep™ protein precipitation plates
- Thermo Scientific™ Accucore™ (U)HPLC columns
- Thermo Scientific™ Acclaim™ C18 (U)HPLC columns
- Thermo Scientific™ Titan3™ syringes
- Thermo Scientific™ WebSeal™ well plates and mats

## Development DMPK/Pre-clinical

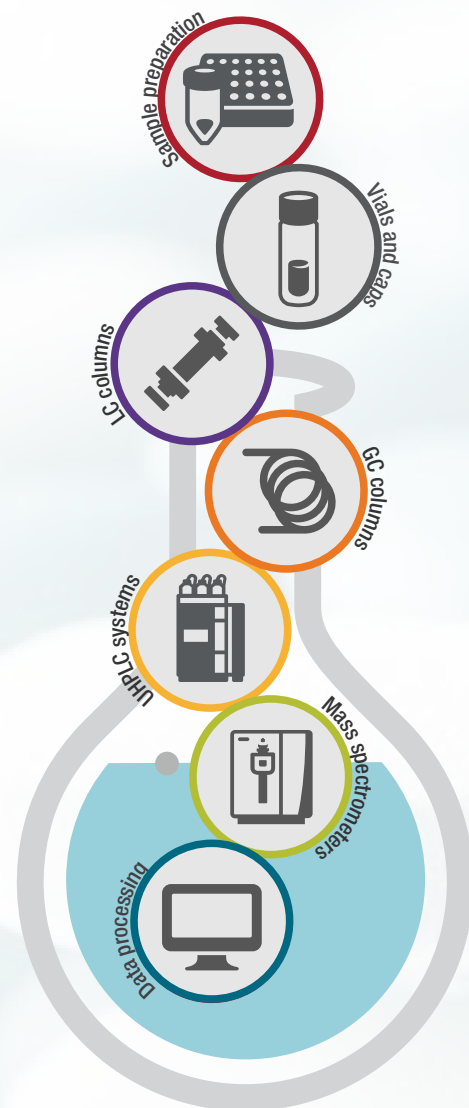
- Thermo Scientific™ SOLA™/SOLA $\mu$  SPE plates and cartridges
- Thermo Scientific™ HyperSep™ SPE cartridges and plates
- Accucore (U)HPLC columns
- Thermo Scientific™ Hypersil GOLD™ (U)HPLC columns
- WebSeal well plates and mats

## Clinical

- SOLA/SOLA $\mu$  SPE plates and cartridges
- Accucore (U)HPLC columns
- Hypersil GOLD (U)HPLC columns
- WebSeal well plates and mats

## QA/QC

- Accucore (U)HPLC columns
- Hypersil GOLD (U)HPLC columns
- Thermo Scientific™ TraceGOLD™ GC columns
- Titan3 syringe syringes
- Thermo Scientific™ SureSTART™ vials and caps



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# Nitrosamine workflow

## Great peak capacity method on Acclaim PA2 columns

A rapid, highly selective, and sensitive method was developed using Thermo Scientific™ Acclaim™ Polar Advantage II (PA2) column, Thermo Scientific™ Vanquish™ Horizon UHPLC system, and the Thermo Scientific™ Orbitrap Exploris™ 120 mass spectrometer for detection and quantitation of nine nitrosamines in commercially available ranitidine drug products. By combining the robust and reproducible chromatography with the 120,000 mass resolving power, fast scanning speed, and sub-ppm mass accuracy of the Orbitrap Exploris 120 system, the resultant method can provide reliable and confident quantitation of nine nitrosamine impurities that meet the September 2020 U.S. FDA regulatory acceptance limits.



Figure 1. XIC of quantitation ion of nitrosamine impurities in 0.5 ng/mL check standard at a mass tolerance setting of 3 ppm



Vanquish Horizon UHPLC system



Orbitrap Exploris 120 mass spectrometer



Acclaim PA2 column



Acclaim guard holder and coupler



SureSTART vial and cap

### Workflow solution

Thermo Scientific instruments	Cat. no.
Vanquish Horizon UHPLC system	—
Orbitrap Exploris 120 mass spectrometer	—
Thermo Scientific columns and guard columns	Cat. no.
Acclaim PA2 column	11341913
Acclaim PA2 guard cartridge	11371733
Thermo Scientific™ Acclaim™ guard holder and coupler	11321933
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 1.5 mL screw vial	17384083
Thermo Scientific™ SureSTART™ 9 mm screw cap	17334043
This workflow includes the newest recommended products	

# Ibuprofen workflow

## Fast and reliable method on Accucore C18 columns

The Thermo Scientific™ Accucore™ C18 column demonstrates excellent performance for the analysis of ibuprofen with minimal peak tailing. The analytical results exceeded the specifications stated in the United States Pharmacopeia (USP) monograph and there was excellent reproducibility between runs. The Accucore C18 columns are therefore an excellent choice for the analysis of ibuprofen and valerophenone.

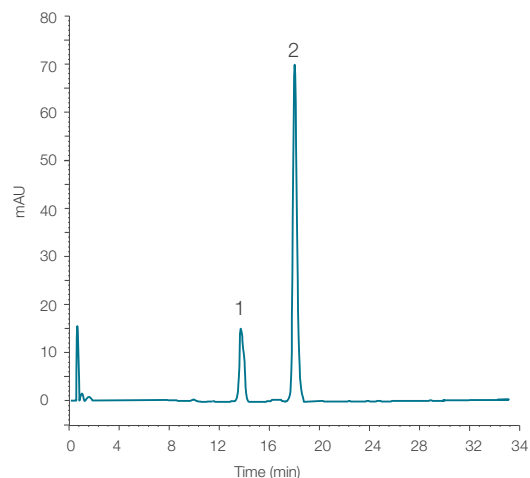


Figure 2. Improved analysis of ibuprofen and valerophenone using a Accucore C18 column



Vanquish Core  
HPLC system



Accucore C18  
column



Uniguard  
direct-connection  
guard cartridge holder



SureSTART  
vial and cap

### Workflow solution

Thermo Scientific instrument	Cat. no.
Thermo Scientific™ Vanquish™ Core HPLC system	—
UV detector	—
Thermo Scientific columns and guard columns	Cat. no.
Accucore C18 column	11347471
Accucore C18 guard cartridge	11667701
Thermo Scientific™ Uniguard™ direct-connection guard cartridge holder	10602864
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 2 mL screw vial	17343893
Thermo Scientific™ SureSTART™ 9 mm screw cap	17383863
This workflow includes the newest recommended products	

# Cepha antibiotics workflow

## Improved peakshape with Hypersil GOLD columns

Hypersil GOLD columns are exceptionally reproducible for reliable chromatography, column after column. This allows the user to be confident that assays developed with the Hypersil GOLD columns will be robust and stable for the life of the assay. Golden features of Hypersil GOLD is the outstanding peak shape that results in greater sensitivity. When peaks exhibit tailing, peak height is reduced, therefore compromising the sensitivity of the analysis. The highly symmetrical peaks provided by Hypersil GOLD columns enhance peak height and allow for optimised peak integration calculations. This can be particularly critical when low concentrations of an analyte are present, for example in an impurity assay.

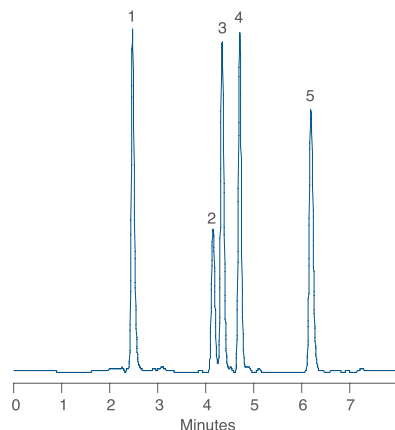


Figure 3. Cepha antibiotics



Vanquish Core HPLC system



Hypersil GOLD column



Uniguard direct-connection guard cartridge holder



SureSTART vial and cap

### Workflow solution

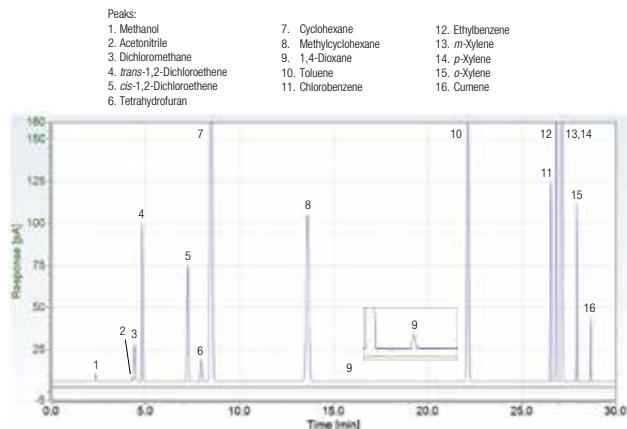
Thermo Scientific instrument	Cat. no.
Vanquish Core HPLC system	—
UV detector	—
Thermo Scientific columns and guard columns	Cat. no.
Hypersil GOLD column	10501695
Hypersil GOLD guard cartridge	11548270
Uniguard direct-connection guard cartridge holder	10602864
Thermo Scientific vials and caps	Cat. no.
SureSTART 2 mL glass screw vial	17343893
SureSTART 9 mm screw cap	17383863

This workflow includes the newest recommended products

# Solvent residue workflow

## Expected separations on TraceGOLD columns

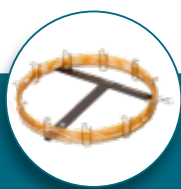
Organic solvents are widely used in the synthesis of pharmaceutical products and cannot always be completely removed during the manufacturing processes. To ensure safety, final products are tested to assess whether the solvents used during the manufacturing processes have been efficiently removed or, if still present, their concentration is within the accepted limits. The Thermo Scientific™ TraceGOLD™ TG-624 column allows to easily meet and exceed USP method resolution requirement ( $R_s \geq 1.0$ ), delivering expected chromatographic separation. And in pair with the Thermo Scientific™ TraceGOLD™ TG-WaxMS GC column the full requirement of the monograph is met.



**Figure 4. Comparison between Class 2A standard solution (blue) and acetylsalicylic solution (green).** Criteria are met as no residual solvent peaks could be detected in the test sample.



TRACE 1600 gas chromatograph with TriPlus system



TraceGOLD column



Super Clean gas cartridge filter



SureSTART vial and cap

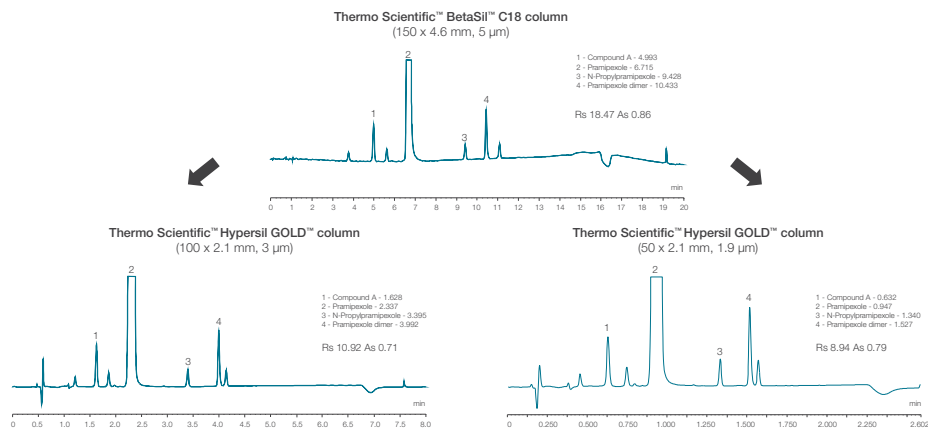
### Workflow solution

Thermo Scientific instrument	Cat. no.
Thermo Scientific™ TRACE™ 1600 gas chromatograph with Thermo Scientific™ TriPlus™ system	—
Thermo Scientific GC columns and guard columns	Cat. no.
TraceGOLD TG-624, TG-624SiIMS GC columns	15224523
TraceGOLD TG-WaxMS GC column	10209234
Thermo Scientific™ GuardGOLD™ capillary column	10221245
Thermo Scientific GC accessories	Cat. no.
Thermo Scientific™ nut	15125256
Thermo Scientific™ Super Clean™ gas cartridge filter with base	10344093
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 20 mL crimp vials	17323803
Thermo Scientific™ SureSTART™ 20 mm crimp cap	17333923
This workflow includes the newest recommended products	

# Learn how to modernize your method

## Reduce time and solvent usage with newer technology columns

By modernizing an older USP monograph after the regulation provided in USP 621 you can reduce the run time and reduce solvent consumption greatly by migrating from a 5 µm to a 3 µm column. Moving to a UHPLC column will further increase time and solvent saving. The new US Pharmacopeia revision, due to release on December 1<sup>st</sup>, 2022, allows for modernization of both isocratic and gradient method. An example of the modernization of for organic impurities of Pramipexole dihydrochloride is shown below.



## How to do the calculation

### Moving from original method to improved HPLC technology

#### Calculate new flow

When changing the particle size and ID of your column, you will have to adjust for flow. This is done by this equation:

$$F_2 = F_1 \times \left[ \frac{(dc_2^2 \times dp_1)}{(dc_1^2 \times dp_2)} \right]$$

F<sub>1</sub>= Old flow rate

F<sub>2</sub>= New flowrate

dc<sub>1</sub>= Inner diameter of column originally used

dc<sub>2</sub>= Inner diameter of used column

dp<sub>1</sub>= Particle size used in original method

dp<sub>2</sub>= Particle size used in modernized method

By simply entering in data in the equation we arrive at the new flow. For our selected column for modernization Thermo Scientific Hypersil GOLD C18 column, 3 µm, 100 mm x 2.1 mm ID this will be:

$$F_2 = 1.5 \frac{\text{mL}}{\text{min}} \times \left[ \frac{(2.1 \text{ mm ID}^2 \times 5 \mu\text{m})}{(4.6 \text{ mm ID}^2 \times 3 \mu\text{m})} \right] = 0.52 \text{ mL/min}$$

#### Calculate new gradient

When modernizing your method, it is important to adjust your gradient to the new run time of the method. This way we assure that separation remains as required. This is done by first calculating the new gradient time, t<sub>G2</sub>. Now we have t<sub>G2</sub> we can calculate out new times for our gradient.

$$t_{G2} = t_{G1} \times \left( \frac{F_1}{F_2} \right) \times \left[ \frac{(L_2 \times dc_2^2)}{(L_1 \times dc_1^2)} \right]$$

t<sub>G1</sub> = 1

t<sub>G2</sub>= New gradient time

F<sub>1</sub>= Old flow rate

F<sub>2</sub>= New flowrate

L<sub>1</sub>= Length of column originally used

L<sub>2</sub>= Length of used column

dc<sub>1</sub>= Inner diameter of column originally used

dc<sub>2</sub>= Inner diameter of used column

$$t_{G2} = 1 \times \left( \frac{1.5 \text{ mL/min}}{0.52 \text{ mL/min}} \right) \times \left[ \frac{(100 \text{ mm} \times 2.1 \text{ mm ID}^2)}{(150 \text{ mm} \times 4.6 \text{ mm ID}^2)} \right] = 0.4$$

Table 1. Calculation of new time for gradient

B,%	Time (min)	Delta t	New time (min)
40	0	–	0
80	15	15 - 0 = 15	Prior time + Delta t x tG2 = 0 + 15 x 0.4 = 6
40	15.1	15.1 - 15 = 0.1	Prior time + Delta t x tG2 = 6 + 0.1 x 0.4 = 6.04
40	20	20 - 15.1 = 4.9	Prior time + Delta t x tG2 = 6.04 + 4.9 x 0.4 = 8



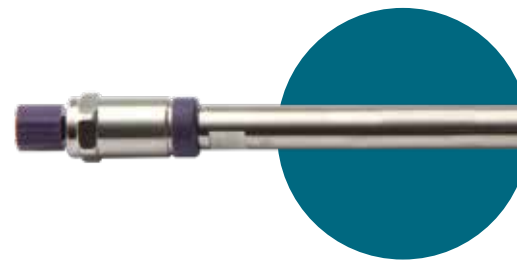
# HPLC columns and accessories

Ibuprofen workflow

Cepha antibiotics workflow

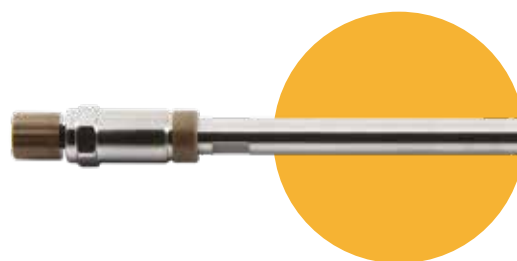
## Accucore C18 HPLC columns

Achieve fast, high-resolution separations at low backpressures using Accucore C18 LC columns. Rugged 2.6 µm solid-core particles ensure high efficiencies and enable compatibility with both HPLC and UHPLC platforms. The high bonded phase coverage provides optimal retention of a broad range of nonpolar analytes across multiple applications. Robust bonding technology and automated packing procedures ensure excellent reproducibility and long column lifetimes.



## Hypersil GOLD HPLC columns

Achieve exceptional peak shape and resolution for your HPLC and LC-MS applications with Hypersil GOLD HPLC columns. These endcapped, ultrapure, silica-based columns deliver significant reduction in peak tailing using generic gradients with C18 selectivity. With their excellent resolution, efficiency, and sensitivity, Hypersil GOLD columns give you confidence in the accuracy and quality of your analytical data.



## Uniguard direct-connection guard cartridge holders

Eliminate the requirement for extra fittings using Uniguard direct-connection guard cartridge holders. They are reusable, stainless-steel guard cartridge holders that attach directly to the analytical column inlet.



### Accucore C18 columns

Format	Length (metric)	Particle size	Cat. no.
HPLC column	100 mm	2.6 µm	11347471
Guard cartridge (4/pk)	10 mm	2.6 µm	11667701

### Hypersil GOLD HPLC columns

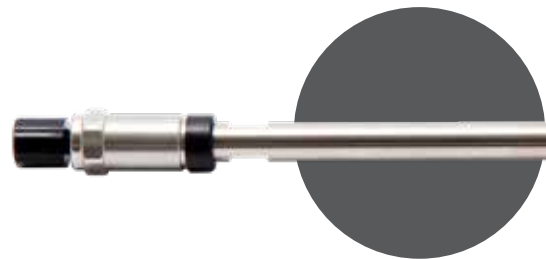
Format	Length (metric)	Particle size	Cat. no.
HPLC column	150 mm	5 µm	10501695
Guard cartridge (4/pk)	10 mm	5 µm	11548270

### Uniguard guard holder

Uniguard direct-connection guard cartridge holder			10602864
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## Acclaim Polar Advantage II (PA2) HPLC columns

Resolve polar and nonpolar compounds in a single run with Acclaim PA2 reversed-phase columns. These high-efficiency, silica-based columns have a polar-embedded stationary phase that operates over a wider range of chromatographic conditions than possible with conventional reversed-phase stationary phases. Its unique chemistry provides enhanced hydrolytic stability from pH 1.5 to 10 with 100% aqueous mobile phases. The column exhibits selectivity that is complementary to conventional C18 columns and excellent peak shapes for both basic and acidic compounds.



## Acclaim guard holder and coupler

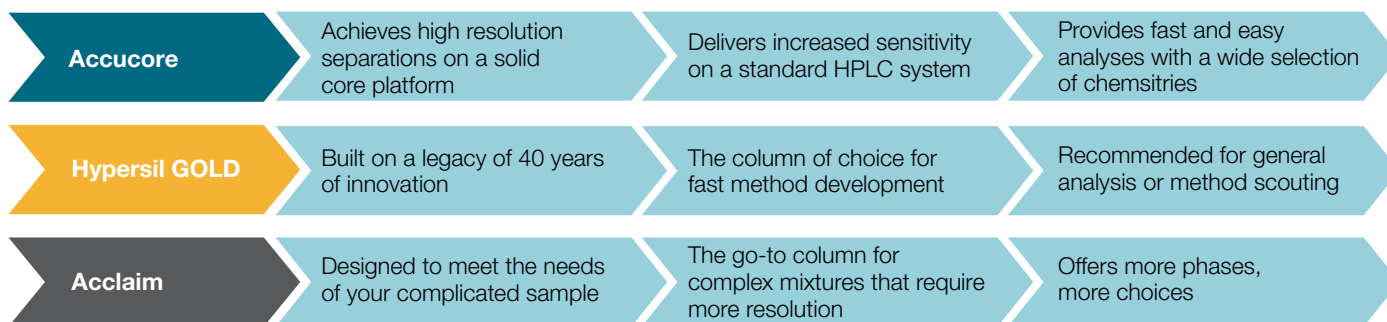
Use the Acclaim guard holder and coupler for your Acclaim guard columns. They can be purchased separately or as a kit.



### Acclaim PA2 columns

Format	Length	Particle size	Cat. no.
HPLC column	100 mm	2.2 µm	11341913
Guard cartridge (2/pk)	10 mm	5 µm	11371733
Acclaim guard cartridge holder-coupler kit V-2			11321933

## Which Thermo Scientific columns meets your separation needs?



## TraceGOLD TG-624 and TG-624SiIMS GC columns

Analyze residual solvents, volatile organic compounds, alcohols, and oxygenates using TraceGOLD TG-624 and TG-624SiIMS GC columns. Both phases offer the low to mid polarity phase, 6% cyanopropylphenyl methypolysilozane.



## TraceGOLD TG-WaxMS GC columns

Analyze FAMES with excellent thermal stability using the TraceGOLD TG-WaxMS GC column.

## GuardGOLD guard columns

Protect your analytical column from damage and contamination from nonvolatile materials using the GuardGOLD capillary columns. The columns facilitate superior analytic performance and protect against column contamination caused by nonvolatile materials, extending the column lifetime. The GuardGOLD capillary columns also focus target analytes at the head of the analytical column, leading to better chromatographic peak shape. Highly deactivated to provide superior inertness, essential for analysis of active compounds, and high maximum operating temperature of 360° C.



### TraceGOLD TG-624 and TG-624SiIMS GC columns

Diameter	Film thickness	Length	Polarity	Temperature	Cat. no.
0.32 mm	1.8 µm	30 m	Mid-polar	320° C	15224523

### TraceGOLD TG-WaxMS GC columns

Diameter	Film thickness	Length	Polarity	Temperature	Cat. no.
0.32 mm	0.25 µm	30 m	Mid-polar	240/260° C	10209234

### GuardGOLD guard columns

Diameter	Length	Cat. no.
0.32 mm	5 m	10221245

## Super Clean gas cartridge filters

Ensure high-purity (99.9999% or 6.0 grade) output gas for optimal GC performance using Super Clean gas cartridge filters. The baseplates can be configured to individual user needs, and there is no contamination during cartridge change. Easy-to-use and cost-effective, Super Clean gas cartridge filters enable fast, tool-free replacement.



## Ferrules and nuts

Use ferrules and nuts to ensure optimal performance. They are available in different materials of various dimension to accommodate a range of instruments, columns and applications.



### Ferrules

Diameter	Material	Size	Cat. no.
0.1 to 32 mm	100% graphite	10	10756334

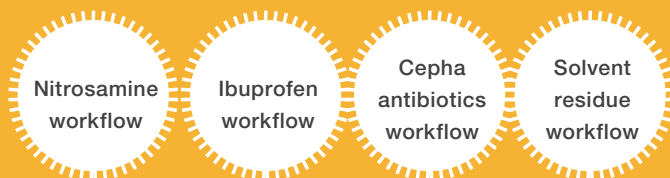
### Nuts for capillary GC columns connections

Diameter	Material	Size	Cat. no.
Retaining nut	Stainless steel	5	15125256

### Super Clean gas cartridge filters

Description	Size	Cat. no.
Gas cartridge filter kit with baseplate	1	10344093
Gas cartridge filter (baseplate not included)	1	10213423

# Vials and caps



## SureSTART 1.5 mL screw microvials and 9 mm caps

Choose SureSTART 1.5 mL total recovery glass screw top microvials, performance level 3, when you need to maximize the injection volume for <2 mL samples.



## SureSTART 2 mL screw vials

Choose SureSTART 2 mL glass screw top vials, performance level 2, to ensure high quality data with an uninterrupted workflow in high-throughput applications using GC, HPLC/UHPLC, and single or triple quadrupole MS systems.

## SureSTART 20 mL glass screw vials

Use SureSTART 20 mL glass crimp top headspace vials in your highthroughput volatile gas analyses. These headspace vials are made to withstand higher temperatures and internal pressures required for volatile gas analyses.

## SureSTART 9 mm screw caps

Use SureSTART 9 mm screw caps with screw vials that have a 9 mm opening.



## SureSTART 20 mm crimp caps

Use SureSTART 20 mm crimp caps with crimp vials that have a 20 mm opening, including our Thermo Scientific™ SureSTART™ 20 mL glass crimp top headspace vials.



### SureSTART vials

Type	Material	Diameter	Total volume	Usable volume	Cat. no.
Screw	Clear glass	9 mm x 32 mm	1.5 mL	1.1 mL	17384083
Screw			2 mL	1.5 mL	17343893
Crimp		20 mm x 75 mm	20 mL	18 mL	17323803

### SureSTART 9 mm screw caps

Septum	Closure material	Thickness	Closure size	Cat. no.
White silicone/red PTFE/Level 3	Blue polypropylene	1 mm	9 mm	17334043
White silicone/red PTFE/Level 2	Blue polypropylene	1 mm	9 mm	17383863

### SureSTART 20 mm crimp cap

Septum	Closure material	Thickness	Closure size	Cat. no.
Blue silicone/clear PTFE; soft	Red aluminum/ magnetic tinplate	3 mm	20 mm	17333923

# Chromatography columns and consumables

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