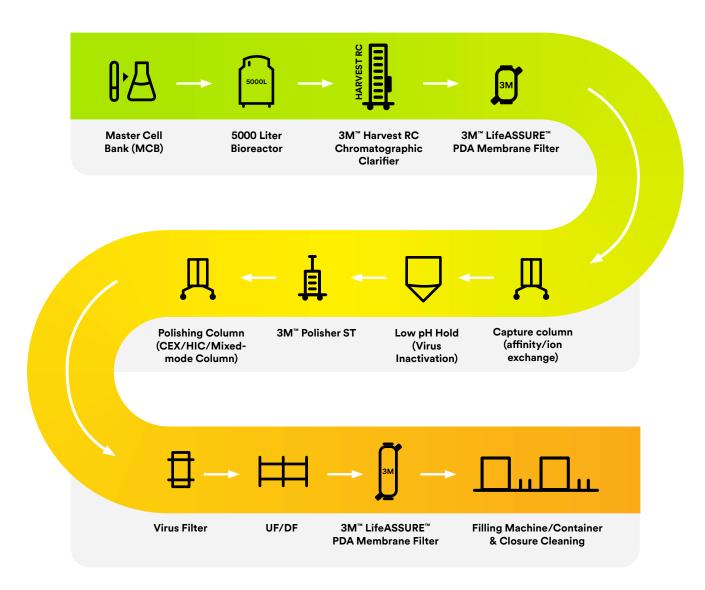
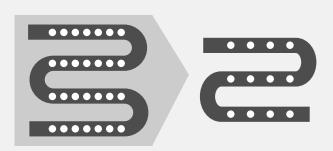




### Reimagine bioprocessing

Standard bioprocessing lines can be fraught with challenges and outdated technology that can't keep up with new developments in higher-titer cell culture. From greater impurities (contaminants) and scale-up issues to prolonged downtime for cleaning and downstream bottleneck, we have a portfolio of solutions that help your line run smoother and faster with excellent purity and yields.





3M's portfolio for mAb/recombinant protein clarification and purification can take a standard bioprocessing line and condense several steps into one, saving you valuable time without sacrificing quality.

# Advanced harvest, clarification and purification technologies

From lab scale-up to commercial manufacturing, we work with you across the entire process train for harvesting and purification to meet the ever-increasing demand to deliver high-quality biopharmaceutical products at an accelerated speed to market.

### Harvest and Clarification Solutions



We offer a comprehensive range of harvest and clarification technologies — from standard filtration to next-gen chromatographic clarification — to help you achieve high yield and purity.

#### **Products:**

3M™ Zeta Plus™ Depth Filter 3M™ Harvest RC Chromatographic Clarifier 3M™ Emphaze™ AEX Hybrid Purifier

### Purification and Contaminant Removal Solutions



Our high-performance polishing and sterile filtration products are ideal for scale-up — delivering advanced purification and contaminant removal. We offer a single-use chromatographic polisher with functionalized membrane technology for efficiency and speed.

#### **Products:**

3M<sup>™</sup> Polisher ST

3M™ LifeASSURE™ PDA Membrane Filter

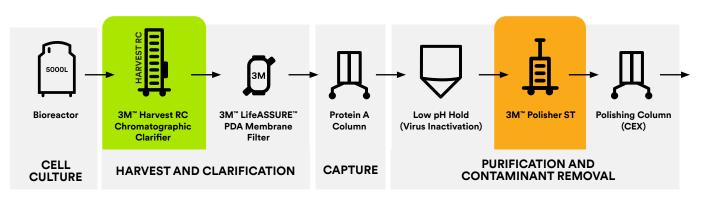


### **Optimizing opportunities**

Whether you're building a new bioprocessing line or streamlining an existing one, we apply our 30 years of purification expertise to help optimize your operation with system-compatible products. Our innovative technologies are designed to improve upon standard bioprocessing by accelerating and condensing steps, leading to increased purity and yield.

### Process compression for intensified mAb manufacturing

Increasingly, you're expected to do more with your manufacturing process – including delivering with greater speed, within budget and under ever-growing challenges. 3M's single-use technology helps you maximize your process train's potential with our high performance single-stage clarification and purification solutions that include intensification options.



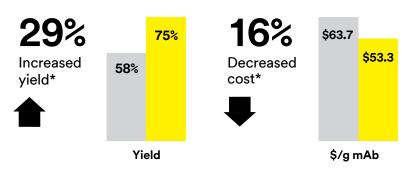
APPLICATION	FEATURED PRODUCTS	
<ul><li>Harvest and Clarification</li><li>Purification and Contaminant Removal</li></ul>	<ul> <li>3M™ Harvest RC Chromatographic Clarifier         Download product brochure     </li> <li>3M™ Polisher ST Download product brochure</li> </ul>	
TECHNOLOGY	KEY BENEFITS	
Single-use fiber chromatography	Process compression, high yield, high purity	

#### **ADDITIONAL BENEFITS**

- Streamlined handling of higher-concentration cultures (between 5-8% packed cell volume)
- Efficient separation of cell, cell debris and DNA from harvest fluid
- Consistent high yield
- Efficient removal of HCP

- Process compression reduced unit operations
- Improved total cost of manufacturing compared to traditional setups
- 3M™ Polisher ST replaces the traditional AEX column
- 3M™ Polisher ST can replace multiple process steps

### See the 3M difference:



Legacy process with 2 stages of depth filters in harvesting & traditional AEX & CEX columns in polishing

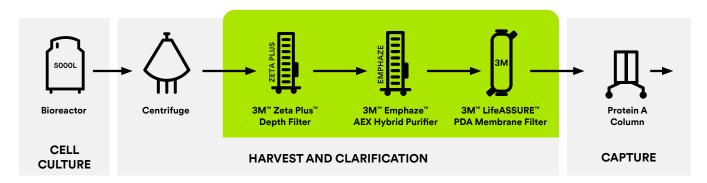


\*Commercial Biosolve Process™ software package from Biopharm Services limited was used for modeling; The results are generated for the hypothetical scenarios. Depending on product and process conditions, the effects shown here may not be realized or may not be realized to the degree shown in the scenarios. 3M data on file.

### **Enhanced clarification** for lines with centrifuge

3M's robust, single-use clarification solutions can help you improve purity while increasing efficiency on your traditional processing line. Our reliable 3M™ LifeASSURE™ PDA Membrane Filters help your control bioburden with fast flow rates. And our depth filters provide you with a full range of pore sizes and media types while eliminating the need for cleaning and validation steps — shortening setup in encapsulated systems.





APPLICATION	FEATURED PRODUCTS	
Harvest and Clarification	<ul> <li>3M™ Zeta Plus™ Depth Filter         Download product brochure     </li> <li>3M™ LifeASSURE™ PDA Membrane Filter</li> </ul>	
TECHNOLOGY	KEY BENEFITS	
Absorptive depth filter, micro porous membrane technology	HCP and turbidity reduction pre and post Protein A column	
BENEFITS OF 3M™ ZETA PLUS™ DEPTH FILTERS	BENEFITS OF 3M™ LIFEASSURE™ PDA MEMBRANE FILTERS	
<ul> <li>3 types of media: SP, LA, ZB</li> <li>Dual layer media enhances contaminant holding capacity</li> <li>ZB range has robust feed quality with higher charge level than SP and LA media</li> </ul>	<ul> <li>High contaminant capacity</li> <li>Gamma compatiable and sterile grades</li> </ul>	

### Increased efficiency for lines with no centrifuge

Help improve your DNA and HCP reduction and increase product purity while reducing cell shear when you add one or two of our depth filters (depending on bioreactor size) and by adding our single-use chromatographic products. You may even be able to skip the second depth filter depending on your concentration of particles — saving steps and increasing process performance.



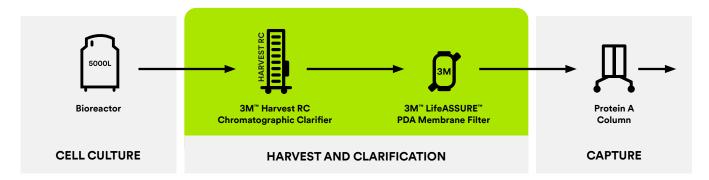


APPLICATION	FEATURED PRODUCT
Harvest and Clarification	3M <sup>™</sup> Emphaze <sup>™</sup> AEX Hybrid Purifier <u>Download product brochure</u>
TECHNOLOGY	KEY BENEFITS
Single-use fiber chromatography	Reduced cell shear and process variability
BENEFITS OF 3M™ EMPHAZE™ AEX HYBRID PURIFIER	
<ul> <li>&gt;10x less HCP post-Protein A</li> </ul>	Reduce challenges for polishing train
<ul> <li>&gt;1,000x DNA reduction post-Protein A</li> </ul>	<ul> <li>Improved process variability by eliminating</li> </ul>
<ul> <li>&gt;10x less residual contaminants on</li> </ul>	centrifuge
Protein A column	Reduce cell shear
Improve clarified cell culture stability	No need to clean and validate centrifuge

## Process compression with single-stage harvest and clarification

You can eliminate the centrifuge in your line and condense steps when you utilize it with 3M's single-stage chromatographic products for harvest and clarification. It simultaneously provides whole cell removal and DNA reduction for high purity.





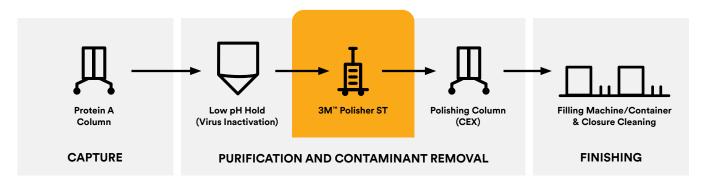
APPLICATION	FEATURED PRODUCT		
Harvest and Clarification	3M <sup>™</sup> Harvest RC Chromatographic Clarifier Download product brochure		
TECHNOLOGY	KEY BENEFITS		
Single-use fiber chromatography	Process compression, turbidity reduction, DNA removal		
BENEFITS OF 3M™ HARVEST RC CHROMATOGRAPHIC CLARIFIER			
<ul> <li>&gt;10x less HCP post-Protein A</li> </ul>	<ul> <li>Process intensification</li> </ul>		
High mAb product recovery (>95%)	<ul> <li>Consistent high yield</li> </ul>		
<ul> <li>Turbidity reduction (&lt;15NTU)</li> </ul>	Predictable scalability		
DNA reduction (<500ppb)			

### Process compression for polishing stage

of operating conditions

Under certain operating conditions, you can compress multiple polishing steps into one with our chromatographic polisher — without sacrificing fluid purity. Our high capacity, yet cost-effective polishing solution replaces the traditional AEX column — providing robust viral clearance and DNA and HCP removal to help you overcome scale limitations.





APPLICATION	FEATURED PRODUCT			
Purification and Contaminant Removal	3M <sup>™</sup> Polisher ST Download product brochure			
TECHNOLOGY	KEY BENEFITS			
Single-use fiber chromatography with functionalized membrane technology	Versatility, viral clearance, problematic HCP reduction, process compression			
BENEFITS OF 3M™ POLISHER ST OVER TRADITIONAL AEX COLUMNS				
<ul> <li>HCP reduction &gt;50% above pH 5</li> </ul>	High salt and low pH tolerance			
<ul> <li>Virus reduction &gt;4 logs</li> </ul>	<ul> <li>Lower buffer consumption</li> </ul>			
<ul> <li>DNA clearance down to less than 10 ppb, or reduction &gt;4 logs or below detection</li> </ul>	<ul> <li>Enables design of a more condensed polishing train</li> </ul>			
Platformability — works in a wide range	<ul> <li>Decreased total cost of ownership</li> </ul>			



# Step into the future with our advanced fiber chromatographic technology

From lab to production scale, the innovative 3M<sup>™</sup> Emphaze<sup>™</sup> AEX Hybrid Purifier, 3M<sup>™</sup> Harvest RC Chromatographic Clarifier and 3M<sup>™</sup> Polisher ST help you streamline your recombinant protein production process, so you can deliver increased batch yields with predictable quality — saving time and money.

PRODUCT	3M™ Harvest RC Chromatographic Clarifier	3M™ Emphaze™ AEX Hybrid Purifier	3M™ Polisher ST	
TECHNOLOGY PLATFORMS	<ul> <li>Quaternary amine         <ul> <li>(Q) functionalized</li> <li>polypropylene nonwoven</li> </ul> </li> <li>0.2 µm polyether sulfone         <ul> <li>(PES) membrane</li> </ul> </li> </ul>	<ul> <li>Quaternary amine         <ul> <li>(Q) functionalized</li> <li>polypropylene nonwoven</li> </ul> </li> <li>Highly asymmetric 0.2 µm polyamide membrane</li> </ul>	<ul> <li>Quaternary amine         <ul> <li>(Q) functionalized</li> <li>polypropylene nonwoven</li> </ul> </li> <li>Guanidinium (Gu)         <ul> <li>functionalized polyamide</li> <li>membrane</li> </ul> </li> </ul>	
MECHANISM	AEX			
MATERIALS	Synthetic			
FEED STREAM	Direct harvest	Post depth filter, post centrifuge	Post Protein A, post-viral inactivation	
SCALABILITY	Linear scalability from lab to multi-capsule commercial production			
APPLICATIONS	<ul> <li>Direct harvest in a single stage</li> <li>Replacement of primary and 2nd depth filters and guard filters</li> <li>Replacement of centrifuge</li> </ul>	<ul> <li>Replacement of 2nd depth filters in harvest and clarification</li> <li>Guard filter to Protein A</li> <li>Bioburden control</li> </ul>	<ul> <li>Replacement of AEX column</li> <li>Replacement of depth filter and membrane filter prior to AEX column</li> </ul>	
FEATURES	<ul> <li>High mAb product recovery (Capsules: &gt;95%; Conical Tube and Well Plate &gt;90%)</li> <li>Consistent cell loading capacity</li> <li>Turbidity reduction (&lt;15NTU)</li> <li>DNA reduction (&lt;500 ppb)</li> <li>Cell shear minimization</li> <li>0.1 &amp; 0.2 µm sterile filter protection</li> </ul>	<ul> <li>Nominal 20-40% HCP and greater than 4 logs DNA reduction</li> <li>Consistent output turbidity (&lt;5NTU)</li> <li>Typically, ≥ 4 LRV endotoxin reduction at low conductivity and neutral pH depending on buffer</li> </ul>	<ul> <li>Operates in pH 5.0 to 9.0 and conductivity 3 to 20 mS/cm process conditions</li> <li>HCP reduction &gt;50% above pH 5</li> <li>Virus reduction &gt;4 logs</li> <li>DNA clearance down to less than 10 ppb or greater than 4 logs or below detection</li> <li>Post-use integrity testable</li> </ul>	

### **Portfolio Overview**

### One step can improve your bioprocessing line.



#### **3M™ Zeta Plus™ Depth Filters**

3M™ Zeta Plus™ Depth Filters include a wide selection of single-use depth filters, featuring a full range of pore sizes and media types. The encapsulated filters deliver high contaminant capacity and throughput, eliminating a cleaning step and cleaning validation, and shorten setup in encapsulated systems.

Learn more about the 3M™ Zeta Plus™ Depth Filters



#### 3M™ Emphaze™ AEX Hybrid Purifier

3M™ Emphaze™ AEX Hybrid Purifiers reduce harvest and clarification steps by replacing the second depth filter, accelerating operations and delivering high purity. Containing a Q-functional anion exchange media and a fine particle, bioburden reduction membrane, the 3M™ Emphaze™ consistently and efficiently reduces DNA, HCP, endotoxin levels and cell debris during manufacturing and downstream processing.

**Learn more about the 3M™ Emphaze™ AEX Hybrid Purifier** 



#### 3M™ Harvest RC Chromatographic Clarifier

3M™ Harvest RC Chromatographic Clarifier is the first one-step fiber chromatographic clarifier that accelerates the mAb harvest and clarification process by improving process efficiencies — like replacing the centrifuge and depth filters while delivering improved yield and purity.

Learn more about the 3M™ Harvest RC Chromatographic Clarifier



#### 3M<sup>™</sup> Polisher ST

3M™ Polisher ST is a fully encapsulated, scalable, single-use anion exchange (AEX) product with two complimentary functionalized media for downstream processing. The AEX- functional membrane with novel ligand combined with a AEX-functional non-woven fiber allows it to perform in high salt conditions, delivers efficient removal of residual contaminants (HCP, DNA) and viral clearance even in the presence of turbidity.

Learn more about the 3M™ Polisher ST



#### 3M™ LifeASSURE™ PDA Membrane Filters

3M™ LifeASSURE™ PDA Membrane Filters leverage single-use cartridges to help control bioburden and deliver process efficiencies through high capacity, fast flow rates and reliable filtration performance across gamma compatible and sterile formats.

Learn more about the 3M™ LIfeASSURE PDA Membrane Filters



### **3M™ Encapsulated System Holders**

3M™ Encapsulated System Holders are designed with operator ease and convenience in mind, accommodating a variety of 3M production capsules for biopharmaceutical processing lines. Multiple configurations of the holder designs allows for flexibility at various production scales, and provide small footprint during use and storage.

**Learn more about the 3M™ Encapsulated System Holders** 



### Take the next step with us.

Our service centers, quality management team and bioprocess application specialists are ready to work with you on your next challenge.

Visit <u>3M.com/bioprocessing</u> or contact your <u>3M</u> representative to connect.

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