Алматы (7273)495-231
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Саранск (8342)22-96-24
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35
Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

Россия +7(495)268-04-70 Казахстан +7(7172)727-132 Киргизия +996(312)96-26-47

www.getinge.nt-rt.ru | | gtw@nt-rt.ru

Технические характеристики на системы биоизоляции в производстве вакцин, устройства асептического переноса DPTE-EXO, DPTE-XS Alpha Port, DPTE-BetaBag, DPTE Beta Containers, DPTE, DPTE TLT, DPTE Transfer Trolley компании GETINGE

Виды товаров: системы переноса, альфа-порты, одноразовые бета-пакеты для стерильной транспортировки, бета-контейнеры, многоразовые канистры для безопасной двусторонней передачи, оборудование для загрузки стерилизатора, транспортные тележки, тестеры утечки.

Taking reliability to the next level

GSS L & R Series Steam Sterilizers for biomedical laboratories

GSS L & R Series Steam Sterilizers help you achieve safety and scientific data integrity. We work together with you every step of the way to give you the solution you need and can trust.

Safe
Easy to use and safe to handle, the GSS L & R Series is designed to secure containment, process result and operator safety.

Reliable
The GSS L & R Series is optimized for the consistent process flow required to secure repeatability in research.

Flexible
Every biomedical facility and country has specific regulations and requirements. Together we customize the GSS L & R to meet your needs.

When safety and results come first

Securing integrity in research

Sterilization and biocontainment are vital components in biomedical research. To discover the cures of tomorrow you need reliable results every day. GSS L & R Series Steam Sterilizers help you achieve a high level of safety and scientific data integrity.

Biomedical facilities are specialized environments with high demands on predictability, containment and safety. Vivariums have to be clean and contamination-free, and researchers and staff protected from pathogens. You need equipment you can rely on to protect data integrity, achieve sterility and uphold critical biosafety levels. Only then can you focus on what is really important – your research.

In addition, your equipment must comply with local and global regulations and be consistent with best practices. At the same time as it satisfies growing demands for a more sustainable use of energy and natural resources.

With their built-in flexibility, GSS L & R Series Steam Sterilizers can be customized to meet your specific requirements and comply with worldwide regulations. Designed around a proven concept, they emphasize safe processes and easy handling, while reducing environmental impact.

For more than 100 years, Getinge has developed equipment to help improve and save people's lives. We are confident that the GSS L & R Series raises the bar for reliable contamination prevention and biocontainment for biomedical research.

Getinge standard control system for GSS Steam Sterilizers

– secure data integrity and connectivity

Getinge offers a B&R control system for steam sterilizers to meet demands for future digitalization, ease of qualification and validation. This makes it easier to acheive high performance, productivity and a streamllined process within your pharmaceutical production or facility.

Operator friendly
GSS Steam Sterilizers are designed around a proven menu structure to enhance easy handling. A user-friendly and intuitive HMI, with presets for common sterilization processes, supports the operator to secure process safety and repeatability in research or in pharmaceutical production.

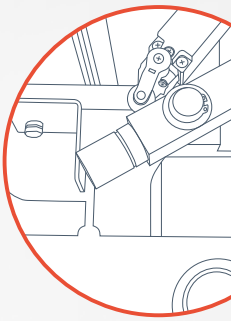
User management
The B&R control system is configured with different sets of access levels with improved user management. The control system can be connected to external systems such as SCADA and BMS through OPC UA standardized protocols. Network printing and network storage can be implemented and adapted for increased flexibility that meets your specific needs and IT infrastructure.

Applications

The sterilizer range is designed for general purpose steam sterilization in laboratory and biomedical research applications.

Application areas	Description	Products
Biopharma production	Component sterilization – Steam sterilizers used for sterlization of parts and components used within pharma production. Typical loads are filling machine parts, tools, containers and solutions. The sterilizer is used as a pass through sluice into the clean production area. Terminal sterilization – Sterilization of finished injectable pharmaceuticals in its final container.	Component sterilization: GSS-P Terminal sterilization: GEV, GEC Closure processing system: CPS
Biomedical research	Sterilization and decontamination in vivarum applications. Typical load is cages and other items related top operation like fodder, bedding, and glassware. Barrier function integrated in equipment for prevention of cross contamination. There is a sub-segment for BSL3/4, where research is being performed on dangerous micro-organizms, with increased containment requirements.	Steam sterilizer: GSS-R, LS-series 700 & 800 Biocontainment applications: GEB
Laboratories	Sterlization in lab applications – Various labs within universities, pharmaceutical production, quality control, food and chemical industry. Typical loads are lab-/ glassware, culture media for sterile testing, liquids in open or closed containers.	Lancer LSS, HS Lab, GSS-L
Heat sensitive goods	Low temp sterilization of heat sensitive goods. Example disposable kits of surgical instruments and other medical devices.	GEE (EtO, Ethylene oxide sterilizer)

Quality without compromise



Vertical or horizontal sliding doors for safety and convenience.

The GSS L & R Series is the latest version of our steam sterilizers. It is optimized to meet the core functionality and safety levels needed in a modern cutting-edge biomedical research environment.

The GSS L & R is engineered with high-quality components chosen to enhance contamination control, encourage a sanitary process, promote best practices and deliver dependable outcomes critical to research, personnel and environmental protection in a biomedical research facility.

Construction and design details, from highly polished stainless steel surfaces to enhanced ergonomic machine interfaces, are carefully integrated into a highly functional system critical to quality assurance.

The GSS L & R can swiftly be put into operation thanks to the refined Quality Process Management System that secures ease of validation and compliance to the intent of the Good Automation System and ensures compliance to global and regional regulations.

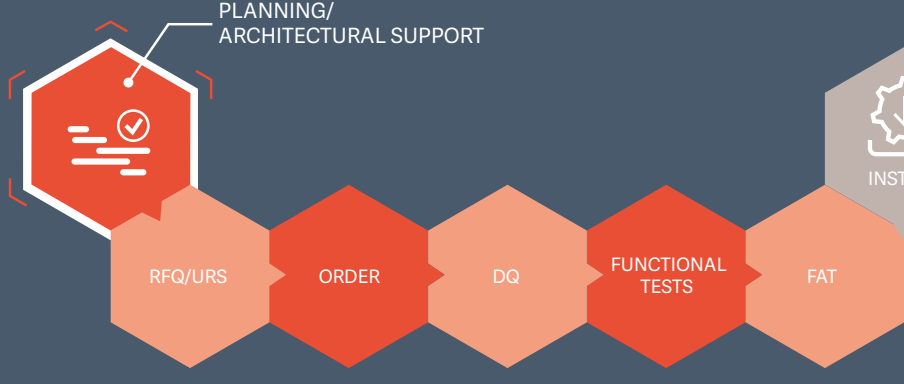
The result is an improved process and solution, designed for easy use and integrated in a controlled biomedical research environment. It is also engineered to reduce your eco-footprint, with several factors that optimize energy and water use, including efficient insulation and minimal mass of pressure vessel.

Stainless steel components are the foundation of reliable piping systems.

With you every step of the way

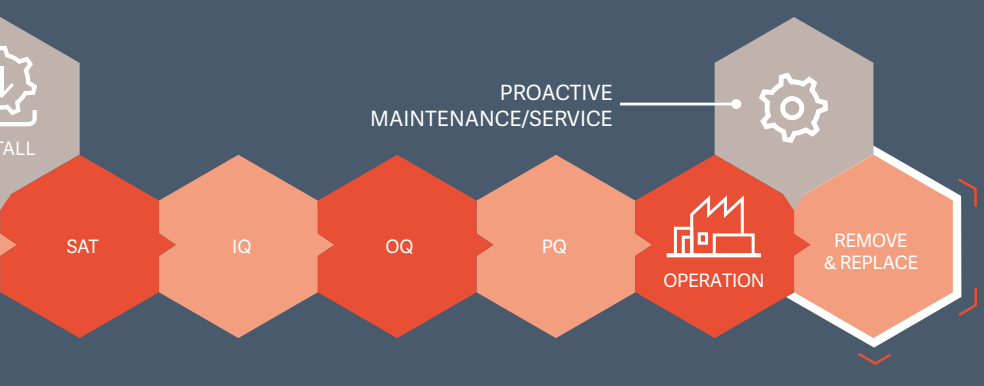
Securing the right level of biosafety for your biomedical facility demands thoroughness and expertise. To optimize space and resources, we help you with architectural layout and planning. We ensure that putting your new GSS L & R Steam Sterilizer into operation is seamless and consistent with best practices every step of the way.

Our support also includes functional tests in our factory, and service to maintain machine uptime through regular and proactive service.



User-friendly display and intuitive HMI for quick, easy use.

High performance liquid ring vacuum pumps for optimal air removal and short process time.



Examples of core features:

- Program combination adapted for lab and research applications
- Intuitive and user-friendly HMI
- Uniform temperature distribution and accurate process control
- Air removal by highly efficient liquid ring vacuum pump
- Fully automatic leak rate test
- ECO-system, recirculation of vacuum pump sealing water
- Stainless steel process and non-process piping
- Stainless steel chamber construction
- Robot welded and highly polished chamber
- Ergonomic and safe automatic sliding doors

Processes

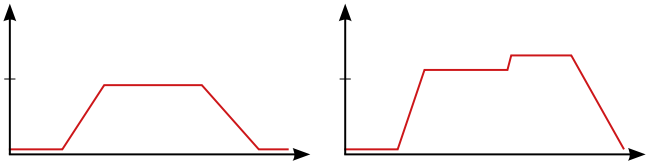
Cycle selection is based on the type of load to be sterilized and how air removal is most efficiently managed for proper sterilization.

Pre-vacuum processes

A saturated steam process with optional pressure pulses to enhance steam penetration covers most sterilization applications where hard or porous goods is to be sterilized. Configurable cycle through adjustable parameters and pressure ramps.

For liquids in open/vented or closed containers

Natural cooling **Jacket cooling**



- Cycles for liquids in open or vented containers are provided as standard. Closed liquids cycles are optional.
- Includes load temperature probe.
- Open liquid process utilizes natural cooling,
- Closed liquid process utilizes support pressure during cooling and indirect jacket cooling.
- Provided with stainless steel filter housing with 0.2 µm sterile filter for support air pressure for sterilization of liquids in closed containers.

For multi-use bioreactors

The bioreactor parts and sterilization process itself has challenges like:

- Vented bioreactor vessel
- Liquid bottle
- Tubing

The bioreactor sterilization concept includes a combination of a single pre-vacuum followed by pressure pulses.

- Pre-vacuum removes the majority of ambient air.
- Multiple steam pressure pulses follow the pre-vacuum to remove any remaining air and provide maximum steam penetration into the vessel and flexible tubing.
- To avoid the boil-over effect in liquid media, pressure pulses must be at a pressure level above the saturation pressure for the given liquid load temperature.
- Integrated process yields a complete bioreactor assembly, with liquid media, sterile and ready for service.

For more information see: application brief "Best practices for sterilization of bioreactors"

Loading equipment
– for safe and ergonomic handling

It is vital to protect both product integrity and staff in the biomedical research laboratories.

The loading and unloading trolleys, shelves and racks are designed to optimize a safe work environment and ensure product quality within the biomedical research laboratory,

For ergonimic and safe loading/unloading Getinge provide with the following loading equipment for the GSS R&L-series

- Shelf racks, with additional shelfs and rails to be added if needed.
- Fixed or height adjustable trolley for transportation of shelf racks within the facility.
- Shelf trolleys for pit mounted units
- Trolleys in stainless steel with electropolished shelves
- Multiple shelf placement locations on rack for high flexibility

Designed for flexibility

GSS L & R Steam Sterilizers come in a range of 17 different chamber sizes with a flexible set of options and customization possibilities.

Although there is a basic GSS L & R range for core functionality – with standard chamber capacities ranging from 10 to 400 ft^3/0.4 to 9 m^3 – the built-in flexibility of the GSS L & R allows for customization. Working closely together with you, we design a contamination prevention solution that suits your needs.

Examples of configuration options:

- Single-door or double-door, pass-through models
- Floor or pit-mounted
- Right or left side service access
- Cross contamination barrier (CCB) or bioseal for integration in building
- Door interlock to prevent cross contamination for barrier pass through models
- Integral steam generator options
- In-situ steam sterilization (SIP) of air filter
- In-situ filter integrity test (WIT)
- Effluent retention options for biocontainment applications
- Process for liquids in open or closed containers
- Jacket cooling with water recirculation
- Network connectivity/SCADA
- Data integrity/21CFR Part 11
- Loading equipment: trolleys, shelves and racks

A legacy of engineering

All our steam sterilizers are developed and manufactured in Getinge, Sweden, where it all started in 1904. Since then we have grown to a global company, but still keep the core of our manufacturing close by to ensure quality and control. We take pride in our engineering and give full attention to detail.

Our processes are constantly updated with new technology in full compliance with changing regulations. When visiting our state-of-the-art factory, with a production area of 16,200 m^2, you find the latest welding robots working side by side with engineers and technical experts with welding qualifications applicable to a global market. All production facilities are certified to ISO 9000 and ISO 14000 standards. We work consciously with our manufacturing and supply chain to reduce environmental impact.

The DPTE® System

The original Rapid Transfer Port

GETINGE

The benchmark for sterile transfer

The first choice for risk-free production

Manufacturing technologies are pushing productivity further with ever higher demands on throughput. GMP requirements are also getting stricter. Pharmaceutical companies must find methods to minimize microbial and particle contamination while keeping up the pace in production.
As a result, isolators are now the gold standard for the production of aseptic or toxic products in pharmaceutical factories and biomedical research. To maintain sterility during transfer of sterile products, specialized technology is needed. The DPTE®* system – the first sterile transfer system for validated aseptic transfer along the production chain – has become an industry standard.

* DPTE Double Porte pour Transfert Etanche (Double Door for Leaktight Transfer)

An industry standard

Developed originally to solve the problem of safe and secure transfer of nuclear waste, the DPTE® system is today the norm in the pharmaceutical production industry with more than 40,000 DPTE® Alpha units installed worldwide.
The system is still based on the ability to transfer components via a DPTE® Beta system into and out of an isolator, filling line, RABS*, BSC* or cleanroom via a secure lock with an Alpha Port, but has been continuously refined and developed over the decades.

*RABS Rapid Access Barrier System
*BSC BioSafety Cabinet

DPTE® technology in your production process

Minimized manual intervention
The major cause of microbial and particulate contamination in aseptic processes.

Higher productivity
Operators are not obliged to manipulate components directly and can be freed up for other tasks.

Risk-free production
Sterile transfer with a secure leak-tight interlock further reduces the risk of contamination.

Securing sterile transfer

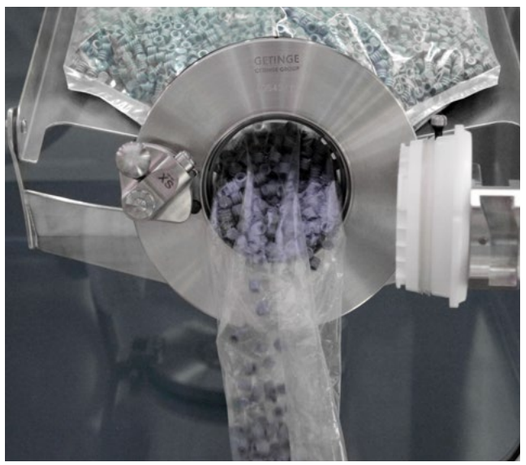
A variety of applications

The DPTE® system enables the user to introduce material into – or to extract material from – an enclosed zone or to connect two devices with identical environments without affecting their ambient characteristics.

The transfer of components with proven leaktightness takes place after docking a Beta container or DPTE-BetaBag® to an Alpha port. The DPTE® system is secure and certified to eliminate any microbiological and particulate risks. A test program has proven that the DPTE® system is not contaminated even after multiple connections and disconnections.

The types of components that can be used for incoming transfers include - but are not limited to - plugs, syringes, pistons, capsules, injectors, stoppers, caps, bottles and plungers, and other medical products as well as toxic/potent products. Outgoing transfers include samples, miscellaneous equipment, waste and bulk products (powder).

Liquid transfer using the DPTE® system (courtesy Octapharma)



Sterile components transfer system

Component transfer at customer site (courtesy Octapharma)
DPTE-BetaBag® was first sterilized in a Getinge sterilizer.

DPTE® Alpha

The core of the system

Original DPTE®

The core of the DPTE® system is the Alpha port with its secure interlock enabling totally safe connections and disconnections.

The DPTE® system is based on the interaction of an Alpha part with a Beta part – each fitted with a door, a lock and a sealing function. The Alpha part is mounted on a support – commonly an isolator, RABS, BSC or cleanroom – while the Beta part consists of a container, bag or similar device used for the transfer of components, solids or liquids.

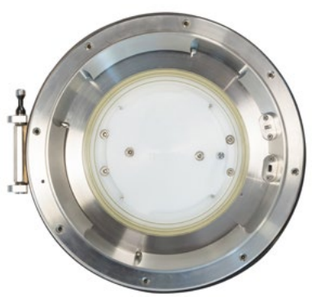
Continuous innovation

The DPTE® system was originally developed in 1963 and has since undergone several further improvements. Due to the demand for increased safety and changing regulations combined with technological progress, Getinge introduced the DPTE® XS – eXtra Safe with an added degree of safety during connection and disconnection.

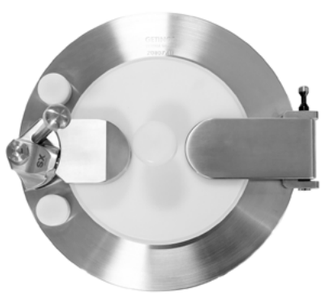
DPTE®-XS - eXtra Safe

DPTE®-XS - Manual 60° Rotation

The Alpha parts and Beta parts are connected by a manual 60° rotation which detaches the doors from their supports and joins them together. Tightness (corresponding to class 1 of 10648-2 standard) is secured by the lip seals of the new assembly. The doors can now be opened without breaking sterility or containment.

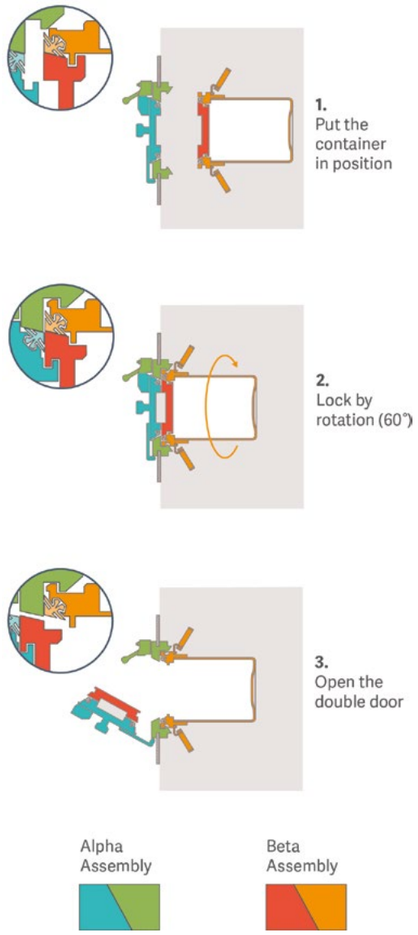


Operator Side



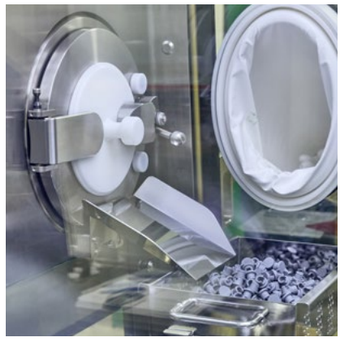
Barrier System Side

Lip seals keep sterility in and contaminants out

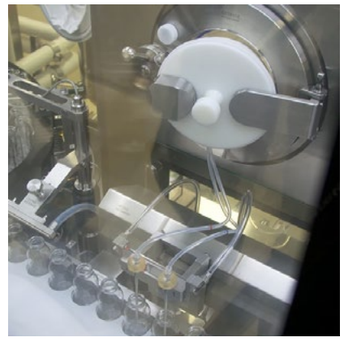


DPTE®-XS Operating Principle

Diameters available (Alpha)	Nom. Dia	105 mm	190 mm	270 mm	350 mm	460 mm



Courtesy Octapharma



Liquid transfer

Microbiological and particulate contamination

The DPTE® system has been rigorously tested for potential microbiological contamination in a three-phase study at the French Agricultural Institute (INRA) in France. Following the same methodology an official study on particulate contamination was conducted at the French Nuclear Safety Institute (LECEV of IPSN) to quantify the efficiency of the DPTE® system.

The results from repeated transfers at higher pressure than used in regular operations showed no microbiological contamination, and – for particulate contamination – that the efficiency ratio for DPTE® was at a level higher than the efficiency of a HEPA* filter, demonstrating its capacity to effectively isolate particulate contamination.

*HEPA High Efficiency Particulate Air

DPTE® Beta containers

The key to safe transfer

Original DPTE®

Transfer of sterile and/or toxic products in and out of a barrier system is one of the most critical aspects of aseptic and confined production. We offer a wide range of re-usable DPTE® Beta containers for bi-directional transfer, in stainless steel and PolyEthylene (PE).

Steam sterilization ready

For aseptic and/or containment applications our reusable PE containers can be sterilized by gamma irradiation or biodecontaminated by H_2O_2. They can be used to transfer HAPIs (Highly Active Pharmaceutical Ingredients), typically powder or in powder form.

Gamma irradiation ready

Container benefits

- Mechanical safety lock to prevent incorrect manipulation
- Compatible with any DPTE® Alpha port of the same diameter
- Bi-directional transfer system for safe handling of sterile and toxic products
- Re-usable, cleanable, cost-effective
- Steam or gamma sterilization ready
- H_2O_2 biodecontamination ready
- Optional racks for steel canisters provide efficient manipulation and sterilization solutions

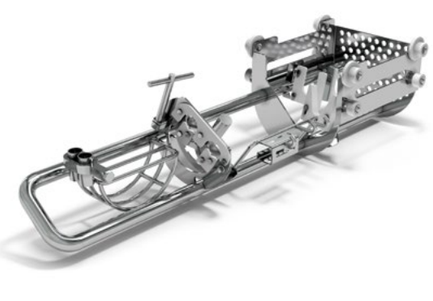
Getinge's stainless steel containers are used to sterilize material before bringing it into the aseptic zone or to remove material from a sterile environment.

Various levels of stainless steel containers and racks are available, from standardized to fully customized. Refer table on page 19.

Hydrophobic filter for steam sterilization

Rounded basket for all levels of containers

Configurable Rack



Customized Rack

DPTE-BetaBag®

A flexible single-use option to increase productivity

Original DPTE®

The DPTE-BetaBag® is a combination of a DPTE® Beta part and a bag for the safe transfer of sterile products or waste material. The DPTE-BetaBag® single-use range is designed for fast contamination-free transfer to maintain high-speed production, increase flexibility and minimize validation costs.

DPTE-BetaBag® 105, multi-layer
Poly-Ethylene filled with components (plungers)

Flexibility and long-term partnership are key

Although typically the DPTE-BetaBag® is made of either multi-layer PolyEthylene, PolyUrethane or Tyvek®, the size, shape and material of the bag vary according to application and production parameters. This compatibility with various applications is based on long-term partnerships with industry leaders. The system also offers safe, bi-directional transfer, i.e. the product can be transferred from the DPTE-BetaBag® to the process zone and vice versa.

Ready-to-use

Components such as stoppers, caps, plastic bottles and plungers can be loaded into a single use DPTE-BetaBag® at the point of manufacture, sterilized inside the bag by the appropriate sterilization method (typically gamma, ethylene oxide or steam), and delivered to the pharmaceutical production site, ready to use.
Using quality control and modern tracing techniques, components are documented as sterile, providing a complete guarantee to the client.

DPTE-BetaBag® 190 Tyvek® filled with components (caps)

Benefits of the pre-filled , pre-sterilized single-use DPTE-BetaBag®

- Complete sterility guarantee
- Increased manufacturing flexibility and scaleability
- Reduced risk of cross contamination
- One sterilization and multiple (up to 5) connections
- Process and production uptime improvement
- No requirement for in-house sterilization of components prior to bagging
- No requirement to biodecontamine the bag before loading products into the aseptic zone
- No cleaning, washing operations needed so no cleaning process validation on site
- Reduced use of chemicals for cleaning
- Maintenance-free
- Minimized operator intervention
- Production surface (footprint) reduction
- Better ergonomy for operators

Guaranteeing safe transfer

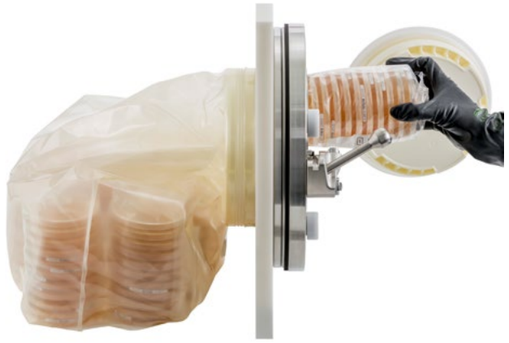
The validation of our DPTE-BetaBag® complies with international regulations and includes:

- Mechanical validation
  - Leak testing of DPTE® Beta unit
  - Leak testing of bag welded onto DPTE®
  - Seal strength of the bag
- Sterility validation (Gamma irradiation cycle between 25 and 50 kGy)
- Microbiological validation
  - Bioburden
  - Endotoxin level
- Particulate validation

Many single-use applications

Validated to comply with international regulations, the DPTE-BetaBag® is used in various applications in aseptic and contained production

The DPTE-BetaBag® is also used to transfer environmental monitoring items, cleaning materials and to handle waste, i.e. safely removing items such as toxic waste, broken vials, ampules, syringes and used wipes from the isolator or filling line.



Environmental monitoring items, pre-sterilized, ready-to-use plates (courtesy of Merck KGaA or its affiliates)

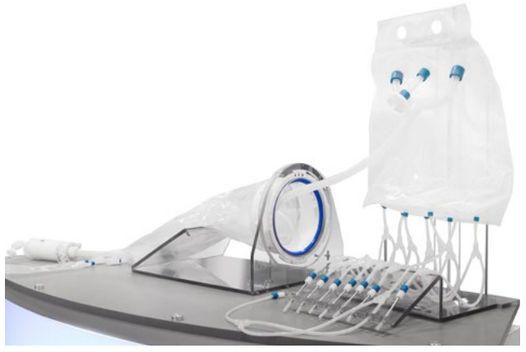
Cleaning materials, pre-sterilized, ready-to-use (courtesy of Texwipe)

Waste removal from an isolator using a DPTE-BetaBag®

The DPTE-BetaBag® contributes to safe transfer of liquids, maintaining sterility between the tank source and the point of filling.

In the aseptic filling process, replacement of all the parts in contact with the product, after use, significantly reduces the contamination risk. Getinge's partners have developed single-use assemblies which are pre-validated, pre-assembled, pre-sterilized systems with tubing, connectors, filters etc. placed inside a DPTE-BetaBag® for easy and secure insertion and removal around the aseptic filling line.

DPTE-BetaBag® for liquid transfer
(courtesy of Merck KGaA or its affiliates)



DPTE-BetaBag® for liquid transfer
(©2019 Saint-Gobain Life Sciences)

DPTE-BetaBag® for liquid transfer (Copyright Pall Corporation)

Sustainability

Is single-use technology viable from a sustainability perspective? Studies* show that single-use products, compared to re-usable stainless-steel products (for example), have "substantially lower energy and water requirements because of the elimination of extensive cleaning and sterilization between each batch production as well as chemicals used during that process".

*"Is Sustainability Possible with Singe-Use Technology", Trisha Glad, Pharmaceutical Online, 12 August 2015

Nearly 60 years of transfer solutions

A legacy of sterility

The DPTE® system is manufactured in Vendôme, France. All sterile transfer parts are rigorously tested and validated in the extended, ultra-modern Vendôme factory.

The first DPTE® system was developed for the nuclear industry in 1963. In the 1970s the pharmaceutical industry realized the potential in this sterile transfer solution, resulting in the production of the first DPTE-BetaBag® in 1998. Getinge manufactures both Alpha and Beta parts in the factory in Vendôme, where the DPTE-BetaBag® range is assembled in ISO 5 and ISO 7 environments for ultra-clean production.

During assembly in the factory, inspections are performed on 100% of production. Inspections consist of leak tests, visual inspection and mechanical and connection tests. Each DPTE-BetaBag® batch is delivered with a certificate of conformity based on total traceability in the supply chain.

The DPTE-BetaBag® is validated on gamma irradiation sterilization, on endotoxins, bioburden and particulate level according to the following standards: ISO 11137 1, 2 and 3, European Pharmacopeia 5th Edition Chapter 2.6.14 with additional constraints on fibers decided by Getinge.

Getinge has invested in ISO 5 cleanrooms in order to comply with the continuously evolving Good Manufacturing Practice (GMP) regulations and to ensure consistently high quality production. We are constantly working on the highest possible level of cleanliness, in order to remain at the forefront of sterile transfer technology, based on a permanent Continuous Improvement Programme.

DPTE® Accessories

To optimize your sterile transfer solution

We are constantly designing and developing accessories to streamline your process while improving operator safety and ergonomics.

DPTE® Tubing with heat sealing machine *for removal of items from the sterile zone*

Cover for autoclavable containers
Protects gasket during sterilization and manipulation

DPTE® Alpha port with flexible membrane
Enables rotating Alpha

Lifting pressure cover
For steam sterilization in place of Beta part seal surface

DPTE® container locking/unlocking key
For secure opening/closing in aseptic zone

Dummy container
Use when decontaminating the seal on the Alpha part

Handles for DPTE-BetaBag®, 190 and 270, multi-layer PolyEthylene and PolyUrethane

DPTE® Transfer Trolley

Safe, Smart, Simple

The hygienically designed compact loading trolley safeguards production efficiency and the integrity of the product inside the DPTE® aseptic transfer system. Variable height and memorization of positions for DPTE® access improve ergonomics and safety.

DPTE® Transfer Leak Tester TLT

Wireless and pipeless

Check the integrity of your Beta container before and after use, with Getinge's wireless, pipeless leak tester. The equipment provides full traceability under FDA 21 CFR Part 11.

Maintaining safe production

Managing and protecting your investment

As a reliable partner by your side, we help you to maintain and optimize the productivity of your equipment throughout its entire life cycle.

The DPTE® transfer system is a critical component preventing cross contamination in the aseptic process. Getinge proposes regular preventive maintenance of Alpha ports and Beta containers to ensure that your transfers are leaktight.

- Leak test before and after the maintenance operation
- Change the lip seal every year (Getinge recommendation)
- Visual inspection of flange and door (lip seal contact surface)
- Functional verification of all inner pins and replacement if needed
- Remounting
- Control of hydrophobic filter (autoclavable containers)

DPTE-BetaBag® Product Range

Direct delivery or via component manufacturers:

- Ready to sterilize (RTS)
- Ready to use (RTU)

Shelf-life:

- 24 months (average)

Bag volumes adapted to applications:

- from 10L to 150L

DPTE® Product Range

			105 mm	190 mm	270 mm	350 mm	460 mm
ALPHA	DPTE®-XS PORT		●	●	●	●	●
BETA	DPTE® Containers	Stainless Steel	●	●	●	●	●
		PolyEthylene	●	●	●	●	●
	DPTE-BetaBag®	Tyvek®	●	●			
		PE/EVOH/PE	●	●			
		PolyUrethane	●	●	●		
	DPTE® Tubing PolyEthylene		●	●	●		
	DPTE® Dummy Container		●	●	●	●	●

DPTE® Beta Stainless Steel Containers: 4 Levels

	Level	Ø	Length 300 mm	Length 400 mm	Length 500 mm	Length 600 mm	Length 700 mm
1	**Standard***	**190**		●			
		270		●			
		350			●		
2	**Semi-standard**	**190**	●	●	●	●	●
		270	●	●	●	●	●
		350	●	●	●	●	●
3	**Configurable** using pre-designed parts	**190**	●	●	●	●	●
		270	●	●	●	●	●
		350	●	●	●	●	●
4	Customized containers and racks, dimensions, parts and finishing to customers' requirements - contact our Sales Team						

* Ø 105 and Ø 460 are part of our range, please contact our Sales Team.

Containers and Racks compatibility

The rack design will match the diameter and length of the chosen container.

		Containers			
		1- Standard	2- Semi-Standard	3- Configurable	4- Customized
Racks	**Glide system**	✓	✓	✓	✓
	Telescopic system	✗	✓	✓	✓
	Roller system	✗	✓	✓	✓
	Configurable rack	✗	✓	✓	✓
	Customized rack	✗	✓	✓	✓

DPTE® Beta Containers Stainless Steel

Re-usable Canisters for Safe Bi-directional Transfer with Optional Racks

GETINGE

DPTE® Beta Containers Stainless Steel

A reliable leaktight sterile transfer solution

Getinge's stainless steel DPTE® Beta Containers allow for efficient loading and unloading of components and equipment into a sterile zone.

They provide security during autoclaving and when transporting items from one containment area to another. The canisters are compatible with any DPTE® Alpha port of the same diameter. Safety interlocks prevent manipulation errors.

The reusable stainless steel containers are engineered for steam sterilization processes. The good mechanical resistance allows safe transfer of heavy and complex parts.

- Integrated hydrophobic sterile filter allows steam to enter the container and maintains sterile conditions after the sterilization process.
- Can be sterilized by autoclaving or H_2O_2

Stainless steel container for transfer of liquid drug products from tank to filling line, simplifies cleaning by SIP (Sterilize In Place) of the entire assembly.

A modular design to fit your specific needs

Level 1

Standard containers

- Standard lengths
- Container body 1mm thick
- Handles: attached to flange
- Autoclavable (perforated bottom, filter connection, protective housing)
- Option: glide system rack

Level 2

Semi-standard containers

- Pre-defined lengths
- Container body 1mm thick
- Handles: selection available, attached to flange
- Autoclavable or H_2O_2 sterilizable (H_2O_2 non-perforated bottom, protective housing)
- Option: racks

Level 3

Configurable containers using pre-designed parts

- Pre-defined lengths
- Container body 2 mm thick
- Handles: selection available, may be attached anywhere on the container
- Autoclavable or H_2O_2 sterilizable
- Option: dismountable bottom
- Option: additional clamp, may be attached to side and/or bottom
- Option: racks

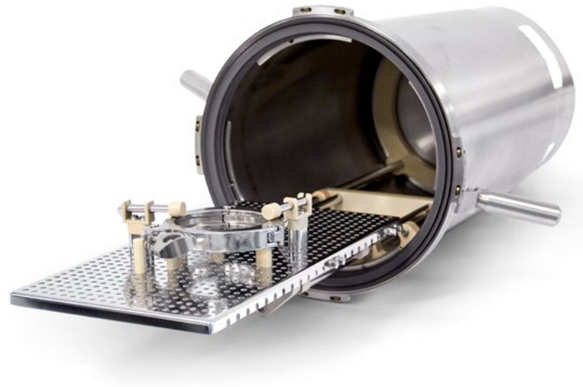
Level 4

Customized containers

- Racks, dimensions, parts and finishing to customers' requirements

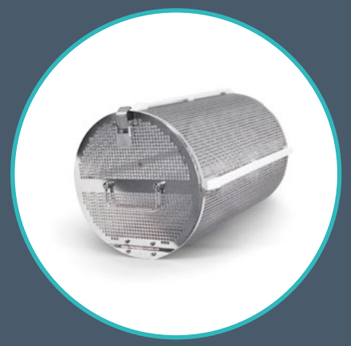
Racks for Stainless Steel Containers

Safely load, sterilize and unload your equipment and components



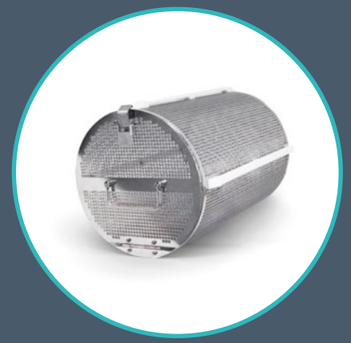
The optional racks provide you with a solution for efficient and ergonomic loading and unloading of components, tools etc. Items are held securely in place inside the container, enabling complete access by steam during autoclaving, leaving no hidden zones so that steam and air can circulate efficiently.

Level 1

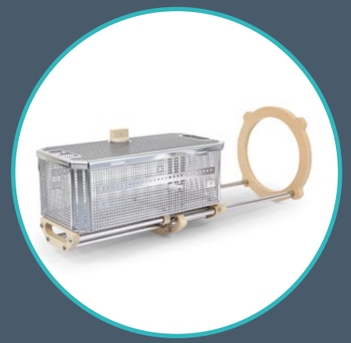


Glide System
The only rack available for all levels of container. This rounded basket can handle stoppers, caps, etc. The basket can be pulled out of the container to move the parts directly into the hopper of the filling line.

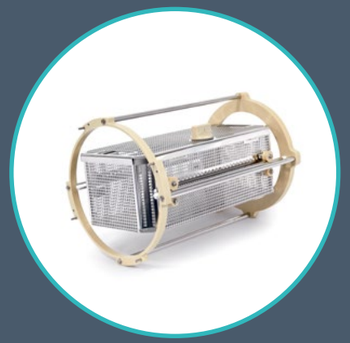
Level 2



Type A: Glide System
This rounded basket can handle stoppers and caps, etc. The basket can be pulled out of the container to move the parts directly into the hopper of the filling line.

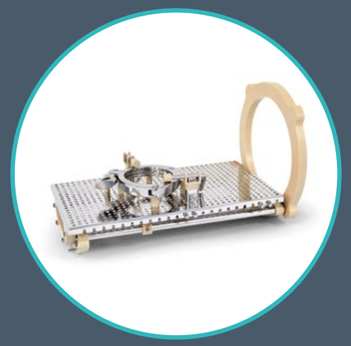


Type B: Telescopic System
The basket can be pulled out of the container but remains attached to it. The operator has access to the full rack space.



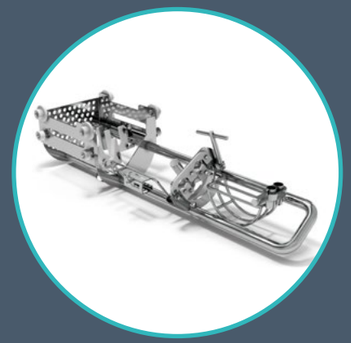
Type C: Roller System
The basket slides on a rail and can be separated from the container. The operator can easily use it outside the container.

Level 3



Configurable Rack
A perforated plate adapted to the length and diameter of the container, the configurable rack can handle variably sized components using repositionable spacers and pins. This rack provides a useful solution adaptable to an almost infinite variety of items of equipment.

Level 4



Customized Rack
The example shown was designed for a complete tool set including funnel, scissors, spouts etc. Other potential loads include machine parts, small tools for environmental monitoring, needles and petri plates.

Containers & Racks Compatibility

DPTE® Beta Containers Stainless Steel

Lengths and diameters available

	Level	Ø	Length 300 mm	Length 400 mm	Length 500 mm	Length 600 mm	Length 700 mm
1	Standard*	190		•			
		270		•			
		350			•		
2	Semi-standard	190	•	•	•	•	•
		270	•	•	•	•	•
		350	•	•	•	•	•
3	**Configurable** using pre-designed parts	190	•	•	•	•	•
		270	•	•	•	•	•
		350	•	•	•	•	•
4	Customized containers and racks, dimensions, parts and finishing to customers' requirements - contact our Sales Team						

* Ø 105 and Ø 460 are part of our range, please contact our Sales Team.

Containers and Racks compatibility

The rack design will match the diameter and length of the chosen container.

		Containers			
		1- Standard	2- Semi-Standard	3- Configurable	4- Customized
Racks	Glide system	✓	✓	✓	✓
	Telescopic system	✗	✓	✓	✓
	Roller system	✗	✓	✓	✓
	Configurable rack	✗	✓	✓	✓
	Customized rack	✗	✓	✓	✓

DPTE® System Accessories

DPTE® Transfer Trolley

The hygienically designed compact loading trolley safeguards production efficiency and the integrity of the product inside the DPTE® aseptic transfer system. Variable height and memorization of positions for DPTE® access improve ergonomics and safety.

DPTE® Transfer Leak Tester TLT

Check the integrity of your Beta container before and after use, with Getinge's wireless, pipeless leak tester. The equipment provides full traceability under FDA 21 CFR Part 11.

Gasket Protection Cover

Protect the gasket of your stainless steel container during autoclaving, storage and transportation with the metal cover that is simple to apply and remove.

Container Key

The key accessory enables you to open and close DPTE® Beta containers easily and safely.

Re-usable PE Beta containers

are also available.
Please contact our Sales Team.

Washing & Sterilization

Getinge recommends using the GEW 101210 Washer/Dryer and the GSS P Steam Sterilizer for the washing and sterilization of a DPTE® Stainless Steel Container.

Getinge GEW 101210 Biotech/ Laboratory Washer-Dryer

GSS P Steam Sterilizer for pharmaceutical production

Safe. Smart. Simple.

Original DPTE® aseptic transfer

DPTE® Transfer Trolley

The smart, mobile transfer platform for use with all DPTE® Beta solutions.

Using the DPTE® Transfer Trolley safeguards optimum production efficiency and filling line uptime, guaranteeing the complete integrity of the product inside the DPTE® aseptic transfer system.

GETINGE

DPTE® Transfer Trolley

Its ergonomic, power-assisted design enables easy handling of heavy and fragile loads within confined spaces, while its smart functions help speed-up manual aseptic zone processes.

The DPTE® Transfer Trolley is Safe, Smart and Simple.

Safe

Prioritise safety for your people, processes and products.

This solution is power-assisted with enhanced ergonomics for ease of handling. Using it is almost effortless and, because it's part of the full DPTE® system, you never have to worry about breaking sterility or containment.

Smart

Work smarter with power-assisted controls.

Its ease of maneuverability reduces aseptic zone disruption and increases production uptime. Operators gain full command of fine-tuned positioning to achieve the elevations and tilts they need, and can store precise alignments to its onboard memory.

Simple

Optimise production, your way.

Only the DPTE® Transfer Trolley combines two aseptic transfer solutions in one product through its cross-compatibility with DPTE-BetaBag® and DPTE® Beta containers (3 diameters). You get double the utility for multiple applications, all within a small, compact footprint.

DPTE® Aseptic Transfer System

The flexibility of the DPTE® Transfer Trolley extends the value of all DPTE® Alpha port environments by combining support for both single-use DPTE-BetaBag® and DPTE® Beta container solutions.

Key facts

- Available as one single model with two different configurations
- Fast changeover between Container and Bag platforms (< 2 minutes)
- Compact footprint: 592 mm x 908 mm
- Lifting interval: 900 mm to 1800 mm, max. lifting capacity 60 kg
- 24-hour battery autonomy and mains power cable back-up
- IP66 Electrical Components Index compliant
- Onboard memory for efficient docking
- Push button controls on the trolley handle
- Cable Remote Control included
- Anti-static wheels

DPTE-BetaBag® configuration

DPTE® Beta container configuration

GETINGE

DPTE® Transfer Leak Tester (TLT)

Patient safety rhymes with process integrity

GETINGE

DPTE® Transfer Leak Tester (TLT)

Wireless and pipeless integrity tester for DPTE® Alpha and Beta containers

Meet current and future regulations

Patient safety is ensured with an unbroken chain of sterility throughout the process. Quality of production batches must be secured during every step. We know you are under pressure from ever-increasing demands on testing for process integrity. Not least from the new Annex 1 Consultation document of the GMP.
This is why the modernized, wireless Getinge TLT is designed to meet these demands and secure the ease and convenience of checking the integrity of both DPTE® Alpha and rigid Beta parts using pressure with reliable and accurate repeatability.

Getinge's DPTE® Transfer Leak Tester (TLT)

During contained transfer of materials into or out of isolators or other classified environments, or during aseptic container storage between processes, the new operator-friendly TLT allows you to check the integrity of the DPTE® systems prior to or after the production cycles.

- Safe production and process control with a reliable, repeatable, traceable leak detection systems
- Simple and easy to install on both DPTE® Alpha and Beta container, whatever the orientation of the DPTE® assembly tested
- Wireless, paperless and pipeless (no cables and pipes between the remote head and the main unit)
- Full traceability compliant with FDA 21 CFR part 11 and EU Annex 11
- Modern tool supporting the equipment integrity and preventive contamination control strategy as recommended by the international guidelines*
- Compatible with all DPTE® Alpha and rigid Beta parts on the market (105 - 350 mm)
- Based on pressure decay method according to ISO Guidelines
- Full connectivity and traceability with the HMI available either with an external tablet or with onboard version, integrated (through SCADA) for Getinge isolators
- Trolley available with 4 charging stations

* European Commission, EudraLex, Volume 4, EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 1, Manufacture of Sterile Medicinal Products, December 2017 (draft for comment).
FDA Aseptic Processing Guidance
PIC/S Pharma Inspection Convention Cooperation Scheme, Section 9.5.3

DPTE®-EXO with Sleeveless DPTE-BetaBag

Automated and externally operated alpha port for secure and optimized aseptic transfer

GETINGE

Open the door to the future

Supporting the pharma industry transition

Your organization is facing increased demands on throughput and automation while GMP requirements become stricter.

Pharma 4.0 is changing the way goods are produced, and the pharmaceutical industry is now increasingly shifting to integrated and automated production systems.

The industry evolves: the next generation of pharmaceutical manufacturing needs greater flexibility to switch production quickly from one drug to another, gloveless processes to reduce human intervention in the aseptic environment, and connected traceable solutions compliant with the latest regulations.

The total solution DPTE-EXO with sleeveless DPTE-BetaBag is an automated and externally operated rapid transfer port and provides a secure, reliable, and automated transfer solution. Its external opening function was designed to significantly reduce the risk of contamination while its connectivity offers a greater degree of traceability and data analysis.

Discover how the DPTE-EXO with sleeveless DPTE-BetaBag supports your efforts to build a safe, automated, and compliant filling line.

Reducing the risk of contamination

with automated aseptic transfer

Automated processes improve operational efficiency

The alpha port with automated external opening combined with an optional funnel provides operational efficiency by reducing manual intervention.

DPTE-EXO has a number of smart controls governing its safe and efficient door opening and closing and funnel movements. It also features a specific program with an open door and funnel position suitable for the enclosure bio-decontamination cycle.

The motorized process automates the repetitive opening of alpha doors with precise angles unique to your aseptic zone environment. The repeatable movements offer better control of the line and process environment. Easy to use, it requires minimal training for your operator to take advantage of its full potential.

Be certain with full data traceability

Take the guesswork out of monitoring and preventive maintenance by improving connectivity and transparency. Depending on your need, DPTE-EXO is fully integrated, mechanically and electrically, with or without data communication with the filling line's HMI.

Using the line's HMI or the optional portable maintenance display, DPTE-EXO can track operational quality and monitor RTP's status, operating hours, faults, and other events to provide a comprehensive view of operations for auditing and preventive maintenance.

Speed-up your decision-making and gain full access to the system with full traceability and data analysis.

Improved responsiveness for increased safety

DPTE-EXO was designed for product, process, and operator safety. Both digital and mechanical precautions are in place to prevent unauthorized or accidental access, and process contamination is avoided in the event of improper connections, power failures, or safety issues.

With the DPTE-EXO, Getinge is taking the safety of the DPTE System to the next level with a new patented safety feature. Each of the 4 lugs of the Beta flange will be individually detected during the connection to avoid any improper connections and further improve sterile transfer security.

All the movements performed by the DPTE-EXO and its optional funnel are fully controlled. The DPTE-EXO is configured to receive information from the filling line such as an emergency stop and/or safety light curtains. The automated process is interrupted when meeting an obstacle ensuring both process and operator safety. In addition, the alpha port can be switched from automatic to manual mode using the optional portable maintenance display for corrective or preventive maintenance or in case of an emergency.

Traceable and validated solution for safe and compliant production

Extensive validation to ensure compliance

With DPTE-EXO you can remain compliant with evolving regulatory requirements. We perform a thorough validation process – including leak testing, endurance testing, shipping testing, particle generation, and H_2O_2 resistance testing – to ensure that your filling line meets all relevant criteria.

The alpha port is designed to be integrated into an architecture in accordance with FDA 21 CFR part 11 – "Electronic Records, Electronic Signatures – Scope and Application" and Annex 11 – EU Guidelines to Good Manufacturing Practices for Medicinal Products for Human and Veterinary Use "Computerized Systems". DPTE-EXO is GAMP 5 compliant, ensuring that your automated processes run smoothly and securely.

Creating new levels of flexibility

With different port configurations, optional funnels, and an adaptable door opening speed and angle, the total solution gives you the flexibility to optimize your production according to your specific needs.

- Door opening to the right or the left
- Funnel located on top or at the bottom of the port
- Different recipes can be managed using the portable maintenance display enabling specific speed and position control for each actuator (funnel, door, lock)

Full documentation package

- Functional specifications
- Assembly Drawing
- Electrical file (electrical diagram, parameters file)
- Manuals (technical, installation, user), spare parts list
- Vendor data sheets for electrical components
- Control system specifications
- Material certificates
- Other standard and optional documentation

Key takeaways

- Automated aseptic process
- Improved operational efficiency
- Efficient bio-decontamination
- Full filling line integration including optional data communication
- Greater degree of connectivity and transparency
- Easy to use
- Validated and compliant
- Higher levels of flexibility
- Complete traceability and data analysis
- Ensuring product, process, and operator safety
- Enhanced security and quick process recovery

Interlocking elements ensure secure connection

– Preserve sterility and containment

To support the need for gloveless processes, Getinge has developed a sleeveless DPTE-BetaBag. The sleeve has been removed and replaced by the funnel reducing human intervention in the aseptic environment.

The DPTE-EXO with sleeveless DPTE-BetaBag is a fully validated and interlocked system. Together with the dismountable funnel, it offers a total transfer solution from the outside of the aseptic filling area to the processing area.

Sleeveless DPTE-BetaBag

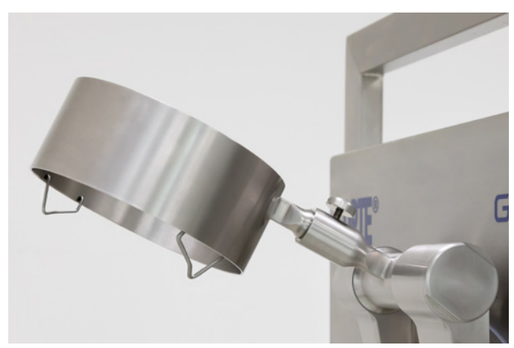
Beta and alpha ports join to form a single validated unit when connected by rotation. The FDA compliant silicone lip seals form a secure connection, allowing the door to be safely opened without breaking sterility or containment. The manually connected sleeveless DPTE-BetaBag comes in RTS (Ready to Sterilize) or RTU (Ready to Use) depending on the bag material for minimum human intervention, increased efficiency, simplified component transfer, and reduced risk of contamination.

Available in:

+ Tyvek or PE-EVOH-PE
+ Diam. 190

Optional dismountable funnels

The DPTE-EXO is the first and only RTP (Rapid Transfer Port) with a fully integrated funnel.
To meet specific needs we offer a high and a low-profile funnel. The funnel protects the alpha/beta seals and its patented FAST system (Funnel Add-on for Smooth Transfer) allows efficient component transfer to the process area (feeder / bowl). It can be positioned above or below the DPTE door. The dismountable funnel can be easily, safely, and quickly released with one hand, and the assembly is fully autoclavable.



A complete solution for sterile transfer

– Compatible accessories

Dedicated accessories streamline processes while improving operator safety and ergonomics.

DPTE Transfer Leak Tester (TLT)

Patient safety is ensured with an unbroken chain of sterility throughout the process. Quality of production batches must be secured during every step. Transfer integrity in rapid transfer ports is essential not only to keep track of the system's lifecycle and its components but also to account for normal wear and tear.

The wireless and operator-friendly DPTE Transfer Leak Tester (TLT) allows you to check the integrity of the DPTE systems before starting the manufacturing batch to ensure safe production and process control.

DPTE Transfer Trolley

Using the DPTE Transfer Trolley safeguards optimum production efficiency and filling line uptime, guaranteeing the complete integrity of the product inside the DPTE aseptic transfer system.

Its ergonomic, power-assisted design enables easy handling of heavy and fragile loads within confined spaces, while its smart functions help speed-up manual aseptic zone processes. Its ease of maneuverability reduces aseptic zone disruption and increases production uptime. Operators gain full command of fine-tuned positioning to achieve the elevations and tilts they need, and can store precise alignments to its onboard memory.

Additional accessories:

+ Handles for 190 PE DPTE-BetaBag
+ Dummy container

Алматы (7273)495-231
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Саранск (8342)22-96-24
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35
Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

Россия +7(495)268-04-70
Казахстан +7(7172)727-132
Киргизия +996(312)96-26-47

www.getinge.nt-rt.ru | | gtw@nt-rt.ru