VELTEK ASSOCIATES, INC.

# TECHNICAL DATA FILES


# DECON-CLEAN®

## Residue Remover and Cleaner
## Pharmaceutical Cleanroom Formula

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## Product Description

**DECON-CLEAN** is designed for and processed to meet the standards required by pharmaceutical, biotechnology, healthcare, and lab animal research operations that demand a cleaning agent to remove residues left behind from disinfecting agents. **DECON-CLEAN** is an effective one-step residue remover when diluted at 1:128 (1 oz. per 1 gallon) of hard or soft water (400 ppm hard as $CaCO_3$). Due to **DECON-CLEAN's** formulation it is an excellent cleaner designed for all washable, non-porous environmental surfaces. Using **DECON-CLEAN**, one can assure that noticeable and unnoticeable residues are removed, thus returning the surface to its original form. Residues left behind from disinfectants, sanitizers, and sporicidies, including Sodium Hypochlorite can be easily removed using **DECON-CLEAN**. Returning the surface to its original form assures that future decontamination will be able to penetrate to the surface.

**DECON-CLEAN** is filled in ISO 5 (Grade A/B, Former Class 100), filtered, and then subsequently terminally sterilized to $10^{-6}$ sterility assurance level. Each lot of **DECON-CLEAN** is sterility tested according to current USP Compendium, is completely traceable, and has been completed validated for sterility and shelf life. **DECON-CLEAN** is delivered each time with a lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

**DECON-CLEAN** is available in multiple container sizes including a 1 gallon, 16 oz trigger spray, unit dose, and a 200 L drum. **DECON-CLEAN** 1 gallon, 16 oz, and 200 L containers come in our one-step, ready-to-use SimpleMix® System that allows for exact and fresh formulations each and every time without handling the concentrate. Each sterile container of **DECON-CLEAN** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Please consult the end of this document for use to remove representative disinfecting agents.

## Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a $10^{-6}$ SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

| **DECON-CLEAN – Residue Remover and Cleaner** | |
|---|---|
| **Certificate of Analysis** | **Result** |
| Appearance: | Clear free of suspended matter |
| Solubility in Water: | Completely |
| % Nonvolatile Matter: | </=20.0% |
| pH of Concentrate: | 9.0-11.0 |
| Specific Gravity @20 degrees: | 1.010-1.040 |
| Expiration Period: | 2 years |

## Uses

**DECON-CLEAN** is designed for use in aseptic filling suites to controlled corridors and can be used for all washable, non-porous, environmental surfaces in order to return the surface to its original form after being disinfected. Examples include on aseptic connections, process lines, walls, floors, and ceilings, counter tops, and stainless steel items.

## Features and Benefits

- Each sterile container is double bagged in easy tear bags
- Packaged quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with Certificate of Sterility, Certificate of Irradiation, and Certificate of Analysis
- Available in our convenient, one-step, ready-to-use, SimpleMix System
- Removes residues from sanitizers, disinfectants, and sporicidies
- Excellent cleaning characteristics
- Multiple convenient container sizes – unit dose, 16 oz, 1 gallon, 200 L
- Available in either sterile or non-sterile

## ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.

## The SimpleMix® System Technology Alternative

Veltek Associates, Inc. has developed the patented SimpleMix System Technology to eliminate measuring and additional containers. It provides for the transfer of the sterile concentrated disinfectant or sporicide and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminates all internal and external sterility concerns. The patented SimpleMix System Gallon, 16 oz, and 200 L systems provide a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The opening on the top of the gallon size contains the concentrate and the bottom reservoir contains the VAI WFI Quality Water. The 16 oz side container houses the concentrate and the bottom reservoir houses the VAI WFI Quality Water. Just open the small chamber cap, push the plunger container completely down until the bottom pops open and the bellows are compressed. 200 L SimpleMix systems are activated through a hose and valve system connecting the cubicontainer of concentrate to the VAI WFI Quality Water. The solution and water mix together. The system design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

## Ordering Information

| DECON-CLEAN – Residue Remover and Cleaner | | |
|---|---|---|
| **Part number** | **Description** | **Qty/cs** |
| DC-01 | DECON-CLEAN, 1 Gallon, Concentrate, Non-Sterile | 4 |
| DC-02 | DECON-CLEAN, 1 Gallon, Concentrate, Sterile | 4 |
| DC-03-4Z | DECON-CLEAN, 4 oz ,Unit Dose, Sterile | 24 |
| DCWFI-SP-11Z | DECON-CLEAN, 11 oz, Aerosol Spray Mist, Sterile | 24 |
| DC-06-16Z-01 | DECON-CLEAN, 16 oz SimpleMix, Attached Trigger, Sterile | 12 |
| DC-07-16Z-01 | DECON-CLEAN, 16 oz SimpleMix, Attached Trigger, Non-Sterile | 12 |
| DC-04-1Z | DECON-CLEAN, 1 Gallon SimpleMix, Sterile | 4 |
| DC-05-1Z | DECON-CLEAN, 1 Gallon SimpleMix, Non-Sterile | 4 |
| DC-100-200L-CI | DECON-CLEAN, 200L, SimpleMix Drum, Sterile | 1 |


DC-01


DC-03-4Z


DC-06-16Z-01

**Veltek Associates, Inc.**
15 Lee Boulevard ● Malvern, PA 19355-1234
Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com

## VAI's Product Label Colors

| Product Name | Bottle/Can Color | Label Background Color | Bar & User Info Color | Text Color |
|---|---|---|---|---|
| DECON-AHOL WFI FORMULA 70% AEROSOL | COOL GREY | PRINTED CAN COOL GREY | | |
| DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON | WHITE | COOL GREY | | |
| DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE | WHITE SEMI-TRANSPARENT | COOL GREY | | |
| DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE | WHITE SEMI-TRANSPARENT | COOL GREY | | |
| DECON-AHOL WFI FORMULA 60% | WHITE | WHITE | | |
| DECON-AHOL WFI FORMULA 91% | WHITE | WHITE | | |
| DECON-AHOL FORMULA 99% | WHITE | WHITE | | |
| STER-AHOL WFI AEROSOL | WHITE | PRINTED CAN WHITE | | |
| STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON | WHITE | WHITE | | |
| DECON-HAND STERILE | WHITE SEMI-TRANSPARENT | PRINTED BOTTLE | | |
| DECON-HAND NON-STERILE | CLEAR | PRINTED BOTTLE | | |
| DECON-HAND ASEPTI-CLEANSE BOTTLE | WHITE SEMI-TRANSPARENT | WHITE | | |
| STERI-OIL | WHITE | WHITE | | |
| STERI-BUFFER | CLEAR | WHITE | | |
| DECON-PHENE | WHITE | WHITE | | |
| DECON-CYCLE | WHITE | WHITE | | |
| DECON-CLEAN | WHITE | WHITE | | |
| DECON-QUAT 100 | WHITE | WHITE | | |
| DECON-QUAT 200C | WHITE | WHITE | | |
| DECON-QUAT 200V | WHITE | WHITE | | |
| HYPO-CHLOR 0.25% | WHITE | WHITE | | |
| HYPO-CHLOR 0.52% | WHITE | WHITE | | |
| HYPO-CHLOR 5.25% | WHITE | WHITE | | |
| STERI-PEROX 3% | WHITE | WHITE | | |
| STERI-PEROX 6% | WHITE | WHITE | | |
| DECON-SPORE 200 PLUS (SPORICIDE) | WHITE SEMI-TRANSPARENT | WHITE | | |
| DECON-SPORE 200 PLUS (DISINFECTANT) | WHITE SEMI-TRANSPARENT | WHITE | | |
| STEEL-BRIGHT | WHITE | WHITE | | |
| STERI-SILICON | WHITE | BLACK | | |
| DECON-GLASS | WHITE | WHITE | | |
| VAI WFI QUALITY WATER | WHITE | WHITE | | |
| STERI-WATER | WHITE | WHITE | | |

# PRODUCT LABELING

## DECON-CLEAN®
## Residue Remover and Cleaner
## Pharmaceutical Cleanroom Formula

(Any specific product label is available upon request.)


**DECON-CLEAN** Family of Products

**Veltek Associates, Inc.**
15 Lee Boulevard ● Malvern, PA 19355-1234
Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com
REV 06Apr2022

# DECON-CLEAN®

## Residue Remover and Cleaner
## Pharmaceutical Cleanroom Formula

**Active Ingredients:**
Water.....87.5%
Potassium Tall Oil Soap.....7.5%
Alcohols, C9-11, ethoxylated.....3.0%
*Other ingredients .....2.0%
**Total.....100.0%**

(*elemental phosphate less than 0.2% by weight of concentrate before use dilution)

Container and Product Sterilized and Distributed by:
Veltek Associates, Inc.
15 Lee Boulevard, Malvern, PA 19355
610-644-8335

**Residue Remove**
**Fragrance Free**

**WARNING.** Causes eye irritation

## PRECAUTIONARY STATEMENTS

Do not get in eyes, on skin, or on clothing. Wash hands, forearms and face thoroughly after handling. If swallowed: Call a doctor if you feel unwell. Store in a closed container. Dispose of contents/container to an authorized waste collection point.

## FIRST AID

**EYES:** Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor/physician.
**SKIN:** Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If irritation persists, consult a doctor.
**INGESTION:** Rinse mouth. Drink plenty of water. DO NOT induce vomiting. Immediately call a poison center or doctor/physician.
**INHILATION:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

**Emergency Response**: 1-866-928-0789 (toll free USA), 1-800-579-7451 (toll free Canada), 1-215-207-0061 (Americas).

SDS No: DC-01-98
**For Industrial Use Only**

## RECOMMENDATIONS FOR USE - Concentrate

Mix 1 ounce of **DECON-CLEAN** with 1 gallon of water (1:128) or mix all 4 ounces with 4 gallons of water. Apply product generously to wet entire surface and use mechanical action to loosen residue. Squeegee off, wipe dry or rinse with clean water and dry.

## DIRECTIONS FOR USE - SimpleMix

**Prepare use solution by following SimpleMix System Container Instructions:**

Trigger Spray Bottle:

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container completely down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.

Gallon Size Bottle:

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping far edge and pulling off.
3. Firmly push small, inner container completely down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.

200 Liter Drum:
(note: To be used with a Veltek Associates, Inc. pump)

1. Close all valves.
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes
10. STOP pump.
11. Close valve 4.
12. To dispense – Open valves 3 and 7. Run pump only when dispensing.

## SIMPLEMIX® 16 oz/473 mL Aseptic Mixing System

For the Exact Formulation of 16 oz/473 mL Disinfectants and Sporicides

## Ready-to-Use Mixing Instructions

1) To prepare use solution, open cap.
2) Peel off inner seal by grasping tab at far edge and pulling off.

3) Firmly push small, inner container all the way down.

4) Replace cap and tighten.

5) Slowly swirl for 15 seconds.

6) Move spray nozzle to open position.

7) Follow directions for use on label.

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15 Lee Boulevard ● Malvern, PA 19355-1234
Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com

## SIMPLE MIX® 1 Gallon/3.79 L Aseptic Mixing System

For the Exact Formulation of 1 Gallon/3.79 L Size Disinfectants and Sporicides

## Ready-to-Use Mixing Instructions

1) To prepare use solution, open cap.
2) Peel off inner seal by grasping tab at far edge and pulling off.

3) Firmly push small, inner container all the way down.


4) Replace cap and tighten.


5) Slowly swirl for 15 seconds.

6) Open small side spout and peel off inner seal, as above.


7) Pour solution from small side spout onto surfaces to be treated or alternate containers.

8) Follow directions for use on label.

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## SIMPLEMIX® 200 L Aseptic Mixing System

For Large Scale Aseptic Manufacturing Environments

## Ready-to-Use Mixing Instructions

Remove drum from double-bag packaging.

Remove cubic container from top of drum. 1) Close all valves. 2) Uncoil hoses.

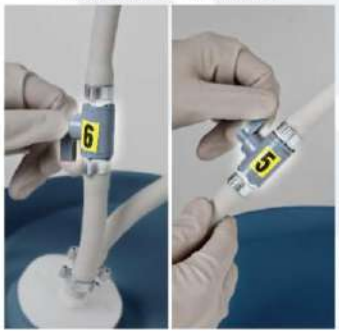
3) Connect center hose to pump between X and Y.

4) Open valve 1, then valve 2, then valve 4.


5) START pump to empty cubic container. 6) When cubic container is empty, turn pump OFF.

7) Close valve 1 and valve 2.


8) Open valve 6 and valve 5.




9) Re-start pump and mix 15 minutes. 10) Stop pump.

11) Close valve 4. 12) To dispense- Open valves 3 and 7. Run pump only when dispensing.


13) Follow directions for use on label.

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# Testing Summary
# DECON-CLEAN

**Residue Remover and Cleaner for Hard Surfaces**
**Sterile Pharmaceutical Clean Room Formula**

## Surface Evaluation for Determining the Residual Levels of VAI Sterile Chemicals and Disinfectants

### Discussion and Purpose of Testing

The aim of this study was to evaluate the cleaning efficiency of the new environmentally friendly and biodegradable **DECON-CLEAN** formula. In accordance with recent EPA regulations (Significant New Use Rule, 25 Sep 2014) the **DECON-CLEAN** formula was updated and the alkylphenol based detergent was replaced with environmentally friendly ethoxylated alcohol surfactant.

Chemical residues can be quantified and appropriate operating procedures can be developed to reduce their existence on surfaces. VAI developed **DECON-CLEAN** residue remover to assure the removal of existing chemical residues. By removing these residues, a class 100 aseptic facility is less likely to transfer existing residues from their initial location to critical manufacturing sites.

### Particulate Impurities

Particulate impurities can cause contamination problems and may provide a nutrient source for existing organisms in the aseptic manufacturing area. Particulate impurities can be removed from solution by filtration. All VAI sterile chemicals and disinfectants receive a level of filtration.

### Chemical Ingredient Residues

Chemical ingredient residues pose a complicated problem associated with both buildup and cross-contamination. The removal of such residues should be considered as a standard practice to eliminate the possibility of these concerns.

### DECON-CLEAN as a Residue Remover

**DECON-CLEAN** has been developed to cope with the removal of residues within the ISO 5 (Grade A/Class 100) aseptic manufacturing operation. The patented formula assures the breakdown of VAI's DECON-AHOL®, STER-AHOL®, DECON-PHENE®, DECON-CYCLE®, DECON-QUAT 100®, HYPO-CHLOR®, STERI-PEROX®, DECON-QUAT 200, Cage2Wash®, Process2Clean® and DECON-SPORE 200® Plus products. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

### DECON-CLEAN's Effectiveness Test Procedure:

**DECON- CLEAN** was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels.

DECON-AHOL® (70% and 91% RTU)
DECON-PHENE® (1:128 Use Dilution)
DECON-CYCLE® (1:256 Use Dilution)
HYPO-CHLOR® (5.25%, 0.52%, and 0.25%)
STER-AHOL® (70% RTU)
DECON-SPORE® 200 Plus (5%)
DECON-QUAT® 100 (2:128 Use Dilution)
STERI-PEROX® (3% and 6%)

## Test Procedure

1. Residue and residue removal were determined gravimetrically.
2. Stainless steel coupons (316L) were used as the test surface.
3. Testing was conducted in a Class 100 laminar flow hood.
4. All appropriate safety precautions were taken. All safety precautions are to be taken referencing safety. This includes gowning, gloves and a NIOSH approved chemical mask.
5. 5 ml of each chemical was prepared and applied to separate stainless steel coupons.
6. The chemicals were permitted to air dry.
7. The chemical residue was determined gravimetrically.
8. Cleaning was performed with **DECON-CLEAN** by two separate methods; spray rinse only and mechanical cleaning.
9. Residue after cleaning was determined gravimetrically.

**Chemical Residue after Drying**

| Chemical Tested | Results |
|---|---|
| DECON-AHOL® 70% (RTU) | ppm of isopropyl alcohol = 0 ppm* |
| DECON-AHOL 91% (RTU) | ppm of isopropyl alcohol = 0 ppm* |
| STER-AHOL® 70% (RTU) | ppm of ethanol = 0 ppm* |
| DECON-PHENE® II (1:128 Use Dilution) | ppm of Phenols and Chlorophenols = 2 ppm |
| DECON-CYCLE® II (1:256 Use Dilution) | ppm of Phenols and Chlorophenols = 3 ppm |
| DECON-QUAT® 100 (2:128 Use Dilution) | ppm of Ammonium Chloride = 3 ppm |
| HYPO-CHLOR® 5.25% | ppm of Sodium Chloride = 252 ppm |
| HYPO-CHLOR 0.52% | ppm of Sodium Chloride = 30 ppm |
| HYPO-CHLOR 0.25% | ppm of Sodium Chloride = 18 ppm |
| STERI-PEROX® 3% | ppm Hydrogen Peroxide = 1 ppm* |
| STERI-PEROX 6% | ppm Hydrogen Peroxide = 1 ppm* |
| DECON-SPORE® 200 Plus (5%) | ppm Peroxyacetic acid = 3 ppm |

** No residue detectable gravimetrically*

## Testing Residue Removal Ability of DECON-CLEAN as a SPRAY RINSE ONLY

After the chemical residue was established on the surface, the surface was cleaned with a RINSE ONLY of **DECON-CLEAN** at a use dilution of 1:128.

| Chemical Tested | Results |
|---|---|
| DECON-AHOL® 70% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| DECON-AHOL 91% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| STER-AHOL® 70% (RTU) | ppm of ethanol = 0 ppm** |
| DECON-PHENE® II (1:128 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-CYCLE® II (1:256 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-QUAT® 100 (2:128 Use Dilution) | ppm of Ammonium Chloride = 0 ppm |
| HYPO-CHLOR® 5.25% | ppm of Sodium Chloride = 1 ppm |
| HYPO-CHLOR 0.52% | ppm of Sodium Chloride = 0 ppm |
| HYPO-CHLOR 0.25% | ppm of Sodium Chloride = 0 ppm |
| STERI-PEROX® 3% | ppm Hydrogen Peroxide = 0 ppm** |
| STERI-PEROX 6% | ppm Hydrogen Peroxide = 0 ppm** |
| DECON-SPORE® 200 Plus (5%) | ppm Peroxyacetic acid = 0 ppm |

** Visual residue spots, not detectable gravimetrically*

## Testing Residue Removal Ability of DECON-CLEAN USING MECHANICAL CLEANING

After the chemical residue was established on the surface, the surface was cleaned with a **DECON-CLEAN** application at a use dilution of 1:128 and using a VEL8-12X12 Dry Wiper with a circular mechanical cleaning action.

| Chemical Tested | Results |
|---|---|
| DECON-AHOL® 70% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| DECON-AHOL 91% (RTU) | ppm of isopropyl alcohol = 0 ppm |
| STER-AHOL® 70% (RTU) | ppm of ethanol = 0 ppm** |
| DECON-PHENE® II (1:128 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-CYCLE® II (1:256 Use Dilution) | ppm of Phenols and Chlorophenols = 0 ppm |
| DECON-QUAT® 100 (2:128 Use Dilution) | ppm of Ammonium Chloride = 0 ppm |
| HYPO-CHLOR® 5.25% | ppm of Sodium Chloride = 0 ppm |
| HYPO-CHLOR 0.52% | ppm of Sodium Chloride = 0 ppm |
| HYPO-CHLOR 0.25% | ppm of Sodium Chloride = 0 ppm |
| STERI-PEROX® 3% | ppm Hydrogen Peroxide = 0 ppm** |
| STERI-PEROX 6% | ppm Hydrogen Peroxide = 0 ppm** |
| DECON-SPORE® 200 Plus (5%) | ppm Peroxyacetic acid = 0 ppm* |

** No visual residue spots*

## Conclusion

It is concluded from the testing performed that the use of **DECON-CLEAN** is extremely effective as a chemical residue remover. Furthermore, the incorporation of mechanical cleaning further reduces the levels of residues as well as any visual, but gravimetrically undetectable, residue spots.

Written By: Boris Polanuyer Date: 05Oct2015

Approved By: Kelly Rocco Date: 05Oct2015

## Additional Documentation

Upon request, the following additional documentation is available:

- Specific product testing reports
- Safety Data Sheets SDS# DC-01-98
- Product validation
- In-use validation
- Sample lot specific documentation packages including Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis

***VAI's Sterile Chemical Manufacturing Division*** - SCMD manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unitdose packages in ISO 5 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents

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