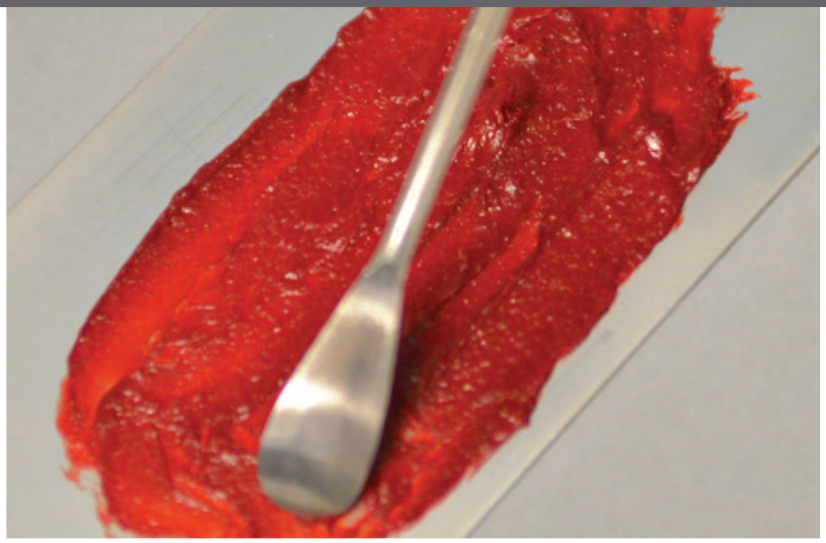
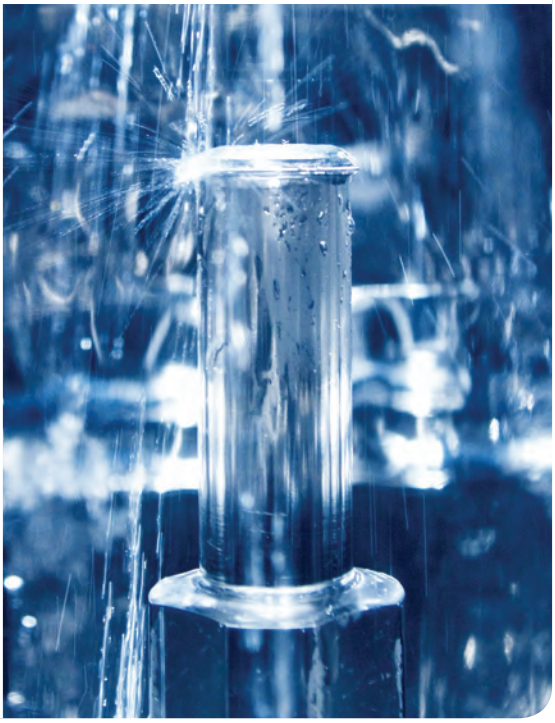
STERIS®

Life Sciences

SETTING THE PACE

Process and Cleaner Evaluation





QUESTIONS & ANSWERS
about the PACE® Evaluation

WHAT IS THE PACE EVALUATION?

The PACE evaluation is the STERIS Process And Cleaner Evaluation. The PACE evaluation helps our Sales Representatives assist you in determining the best cleaning agent and application conditions for meeting your cleaning needs. The PACE evaluation is supported by a fully staffed Technical Service Laboratory and experienced Technical Service Specialists who will work with you and your STERIS Sales Representative to evaluate your needs and to design a cleaning program which meets those needs.

WHEN SHOULD THE PACE EVALUATION BE USED?

The PACE Evaluation should be used to help you:

(1) design a cleaning protocol for a new process,
(2) upgrade the cleaning protocol for an existing process, or
(3) troubleshoot problems that arise with an in-use cleaning protocol.

Objectives might include the following:

- Increased Productivity through reduced cleaning time
- Enhanced Comfort/Positioning relative to cleaning validation
- Improved Consistency/Reduced Downtime through fewer cleaning failures
- Reduced WFI Usage through the use of a formulated cleaner

In all of these cases, the PACE evaluation can help provide an empirical rationale for selecting a cleaner and establishing cleaning parameters such as use temperature and cleaner concentration.

In summary, the PACE evaluation develops cleaning procedures to fit your needs. It is an excellent “first step” in designing a new cleaning program or implementing process change.

SPECIAL CONSIDERATIONS FOR THE PACE EVALUATION

A Safety Data Sheet (SDS) must accompany each chemical residue submitted for PACE evaluation.

1. If an aqueous cleaning system is currently in use, it is highly beneficial to submit a minimum 1000 milliliters or grams of the current detergent along with this completed submission form. This allows comparison screening using the performance of the current detergent as a benchmark. This promotes a higher confidence level concerning performance in the field versus laboratory performance. If faster cleaning, more complete cleaning, lower temperature cleaning, etc., can be empirically demonstrated on a direct comparison basis, the decision to move to field trial based on the laboratory data is reinforced.
2. Note: 3" x 6" (7.6 cm x 15.2 cm) and 1" x 3" (2.5 cm x 7.6 cm) 304 stainless steel coupons (panels) are utilized as the testing substrate for the PACE evaluation These coupons may be field-soiled at your facility and shipped to STERIS in the soiled state. If preferred, STERIS will soil the coupons to your specifications prior to testing. These coupons may be obtained from STERIS by utilizing the order form on the back of this document.

The value of the PACE evaluation is $2000 (U.S. Funds) per sample.

SEND COMPLETED FORM AND SAMPLES TO:

STERIS Corporation
LIFE SCIENCES DIVISION
Attn: PACE Evaluation
7405 Page Avenue
St. Louis, MO 63133, USA

Along with shipping the completed form and samples, you may also e-mail this completed form to: *PACE@STERIS.com*

CONTAMINATION CONTROL PROCESS AND CLEANER EVALUATION FORM

GENERAL INFORMATION

COMPANY/FACILITY DATA:

Company: _____ Division: _____

Facility Location: _____ Dept.: _____

Street: _____

City: _____ State: _____ ZIP/Postal Code: _____

Country: _____

Key Contact: _____ Title: _____

Phone No.: _____ Fax No.: _____

Email Address: _____

THIS SECTION IS TO BE FILLED IN BY STERIS SALES REPRESENTATIVE:

Sales Representative: _____ Territory No.: _____

Phone No.: _____ Fax No.: _____

No. of Items Submitted: _____ Date Submitted: _____

Are items to be returned: ■ Yes ☐ No May items be cut into pieces? ☐ Yes ■ No

Date Results Required: _____ Why? _____

INDUSTRY TYPE

(Please click on only ONE option that applies for samples submitted.)

Pharmaceutical (Prescription & OTC)

Upstream Suppliers/Manufacturer
- ☐ Fine Chemicals (PF)
- ☐ Components & Supplies (PC)
- ☐ Chemical Intermediate (PH)
- ☐ Other (FO) _____

Bulk Active Manufacture
- ☐ Small Molecule–API (BA)
- ☐ Small Molecule–Intermediate (BI)
- ☐ Bio, Extraction (BE)
- ☐ Bio, Fermentation (BF)
- ☐ Bio, Cell culture (BL)
- ☐ Bio, Purification (BP)
- ☐ Bio, Media Preparation (BM)
- ☐ Bio, Buffer Preparation (BB)
- ☐ Other (BO) _____

Agricultural
- ☐ General (AG)

Final dose production
- ☐ Parenteral (DP)

Oral Dose
- ☐ a. Liquid Form (DL)
- ☐ b. Solid Form (DS)
- ☐ Topical (DT)
- ☐ Other (DO) _____

Personal Care
- ☐ Topicals & Creams (CT)

Makeup
- ☐ Base/Foundation (CB)
- ☐ Powder/Rouge (CP)
- ☐ Mascara/Eye Liner (CM)
- ☐ Lipstick (CL)
- ☐ Other (CO) _____

Chemical Manufacturing
- ☐ General (GM)

Medical Device/Medical Products
- ☐ Latex Products (ML)
- ☐ Disposables (MD)
- ☐ Diagnostics (MG)
- ☐ Implants/Critical Devices (MI)
- ☐ Combination Device (CD)
- ☐ Other (MO) _____

Food and Beverage
- ☐ Brewing (FB)
- ☐ General Beverage (FG)
- ☐ Meat, Fish, Poultry Processing (FM)
- ☐ Bakery, Snack Foods (FS)
- ☐ General Foods Manufacturing (FF)
- ☐ Dairy (FD)
- ☐ Other (FO) _____

Lab Animal Research
- ☐ General (LG)

Dietary Supplements
- ☐ Liquid Form (DL)
- ☐ Solid Form (DS)

PROJECT DESCRIPTION AND SAMPLE LIST

CUSTOMER OBJECTIVES/PROJECT OBJECTIVES

Include the facility's primary interest. Interests might include automating the cleaning process, reduced cleaning time, improved cleaning consistency, stronger position relative to validation, etc.)

_____

_____

NAMES OF PRODUCTS SUBMITTED FOR PACE EVALUATION

Attach list of ingredients, if available. A **Safety Data Sheet is mandatory for each product or each hazardous ingredient in the product**. Notify us about highly hazardous materials at PACE@STERIS.com in advance of sending the samples to obtain approval for processing the materials in the laboratory.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____
17. _____
18. _____
19. _____
20. _____

SAMPLE INFORMATION

SAMPLE AMOUNT

Please supply the following sample size for testing:

- If Liquid, send 250 milliliters
- If Solid/Powder, send 100 grams

POWDER/SOLID

If the product is in powder/solid form, the sample should be applied onto coupons as
☐ dry powder ☐ mix with water or organic solvent ☐ both

What solvent should be used? _____ What is concentration of the solid in the mixture? _____

- Recommended solvent should match the solvent that is used in the manufacturing process.
- If solvents other than isopropyl alcohol (IPA), ethyl alcohol, or acetone are required, please send 500 milliliters of each solvent along with the product samples. **Safety requirements in the previous section apply to solvents.**
- If there are special instructions for mixture preparation or coupon coating, please attach.
- In the case of multiple powder samples, specify the solvents/conditions for each sample/group of samples.

SOIL CONDITIONS

Please indicate if the product is cleaned prior to drying onto equipment: ☐ Yes ■ No
Processing condition at a temperature of _____ °C for _____ hours
Dirty hold time at a temperature of _____ °C for _____ hours

Describe any special conditions regarding preparation of sample for testing (soil thickness, multiple layers, etc.)

_____

Additional Comments: _____

COUPONS SOILED BY CUSTOMER

- Soil coupons in accordance with the instructions enclosed; see the last page of this form.
- Submit 1 (one) packet of coupons per sample per cleaning method.

CLEANING PROCESS INFORMATION

"CURRENT" CLEANING PROCESS

Describe* or submit "current" cleaning procedures (S.O.P.): _____

_____

*For description, include the different cycles, times, temperatures, cleaning products, concentrations, water quality and types of equipment.

Customer SOP Attached: ☐ Yes ☐ No

Do you currently use STERIS cleaners? ☐ Yes ☐ No

If yes, which STERIS cleaners? _____

Additional Comments and Concerns: _____

_____

"DESIRED" CLEANING PROCESS

Cleaning parameters in the chart below relate only to the wash step in a cleaning process.

	SURFACE TO BE CLEANED (SS/GLASS/ETC.)	TEMPERATURE RANGE AVAILABLE FOR CLEANING (°C)	IS TEMPERATURE MAINTAINED DURING THE CLEANING CYCLE?	QUALITY OF WATER	PREFERRED CONCENTRATION	MAXIMUM ACCEPTABLE CLEANING TIME
Agitated Immersion			☐ Yes ☐ No	☐ Tap/Potable ☐ Purified/DI		
CIP Spray Ball System ☐ Impingement ☐ Cascading Flow			☐ Yes ☐ No	☐ Tap/Potable ☐ Purified/DI		
Spray Washer ☐ Parts Washer ☐ Tunnel Washer			☐ Yes ☐ No	☐ Tap/Potable ☐ Purified/DI		
Ultrasonic Wash			☐ Yes ☐ No	☐ Tap/Potable ☐ Purified/DI		
Manual ☐ Brush ☐ Wipe			*Not Applicable*	☐ Tap/Potable ☐ Purified/DI		
High Pressure Sprayer or Lance; psi/bar used: _____			*Not Applicable*	☐ Tap/Potable ☐ Purified/DI		
Foam Spray Washer Water Pressure, psi/bar: _____ Air Pressure, psi/bar: _____			*Not Applicable*	☐ Tap/Potable ☐ Purified/DI	*No more*	*No More*

Additional Comments: _____

_____

IMPORTANT NOTE REGARDING SHIPPING SAMPLES TO THE U.S. FOR THE PACE EVALUATION

In shipping samples to the USA for evaluation in the PACE Evaluation, care must be taken to meet all shipping and regulatory requirements. Careful documentation will assure no delays at entry. All documentation must be in English.

1. **The products to be shipped should be identified as Chemical Samples or Biological Samples, and appropriate documents are to be prepared.**

   a. **Chemical Samples**

   All chemicals or items containing chemicals, when imported to the U.S., are regulated by EPA (Environment Protection Agency).

   The following information must be provided for each sample:
   - Clear material identification (name, description).
   - Certification must be made that the samples meet the requirements of the **Toxic Substances and Control Act (TSCA)**. For pharmaceutical products, use precise wording **"I certify that chemicals in this shipment are not subject to TSCA"**.
   - On the invoice, indicate quantity, value with currency, country of manufacturer, HTS (Harmonized Tariff System) number, and price. Include a note such as "Not for sale in the USA", or "Imported for laboratory testing only".
   - MSDS (Material Safety Data Sheet).
   - If applicable, include FDA device listing number and product code.

   For current EPA regulations, please visit the website *www.epa.govoppt/import-export*; open the section "Toxic Substances", then click on "Chemical Import/Export Requirements"; contact TSCA Hotline at (202) 554-1404. Also refer to Technical Tip #3070 for details.

   b. **Biological Samples**

   Materials derived from an animal or produced with animal products or extracts of microorganisms are potentially subject to USDA (U.S. Department of Agriculture) regulations and must be cleared by USDA inspectors at the port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing epizootic livestock or poultry diseases exotic to the United States. **However, chemically synthesized biochemicals or materials that do not contain and were not derived from animal products may enter the country without USDA restrictions.**

   The following information must be provided for each sample:
   - Clear material identification (name, description).
   - Certification must be made that the samples meet the requirements of the **Toxic Substances and Control Act (TSCA)**. For pharmaceutical products, use precise wording, **"I certify that all chemicals in this shipment are not subject to TSCA."**
   - On the invoice, indicate quantity, value with currency, country of manufacturer, HTS (Harmonized Tariff System) number, and price. Include a note such as "Not for sale in the USA", or "Imported for laboratory testing only".
   - MSDS or a statement of inactivation.

For USDA regulations, please visit the website *www.aphis.usda.gov/import_export/index.shtml*. Open the Animal and Animal Product Information section and under the Import an Animal or Animal Product choose Animal Product to find "animal products that do not require an import permit".

The information must be supplied as original statements on producer/shipper letterhead in a clear and concise manner, and be available for review by the USDA Inspector at the Port of Arrival.

IMPORTANT NOTE: No samples containing living microorganisms are processed in our laboratory. MSDS or a statement of inactivation is mandatory for each sample.

2. Please instruct your shippers to provide the above information. Shipping terms are DAP (Delivered at Place). Refer to Technical Tips #3070 (Shipping Samples to The United States for the PACE Evaluation) and #3059 (Packaging Samples for Shipping for PACE Evaluation) for details. **Do not put documents INSIDE shipping containers; attach them on the EXTERNAL SURFACE**.
3. Fax the master airbill number for the package to PACE Evaluation at 001-314-290-4612 or e-mail at *PACE@STERIS.com*. This will enable us to track the package through customs.
4. Have your shipping company notify our customs broker, Hellmann Worldwide Logistics at *steris@us.hellmann.net* (phone: 001-847-768-7900; fax: 001-847-768-7906) when the package is received in the USA.

The above guidelines and regulatory requirements will facilitate a rapid turnaround for your lab testing.

CLEANING COMPARISON ☐ Yes ☐ No

Submit minimum 1000 milliliters or grams of the competitor cleaner along with MSDS (MSDS submission is mandatory).

Competitor Product Name: _____

Manufacturer: _____

EPA Reg. # (if Disinfectant or Sanitizer): _____

Describe current use of product (e.g. concentration, application temperature, method of application, time of cleaning):

_____

_____

Is this product effective? ☐ Yes ☐ No

What improvements does customer seek?

_____

Print and cut along dotted lines and utilize as a shipper label

PACE® EVALUATION

TO: **STERIS Corporation**
LIFE SCIENCES Division
Attn: PACE Program
7405 Page Avenue
St. Louis, Missouri 63133, USA

REQUEST FOR COUPONS

Mail In, Fax to (314) 290-4612, or email PACE Evaluation to PACE@STERIS.com

Sales Representative: _____ Date: _____

Please forward _____ packets of stainless steel panel sets for soiling with product residue. They will then be returned to St. Louis for the PACE Evaluation. NOTE: A packet is being ordered for each product residue targeted for cleaning evaluation. Each packet contains: • 6 x small panels 1" x 3" (2.5 cm x 7.6 cm) • 6 x large panels 3" x 6" (7.6 cm x 15.2 cm).

Ship Coupons to:

Account Name: _____

Account Address: _____

WE CANNOT SHIP TO A P.O. BOX. A STREET ADDRESS MUST BE PROVIDED.

Key Contact: _____ Phone Number: _____