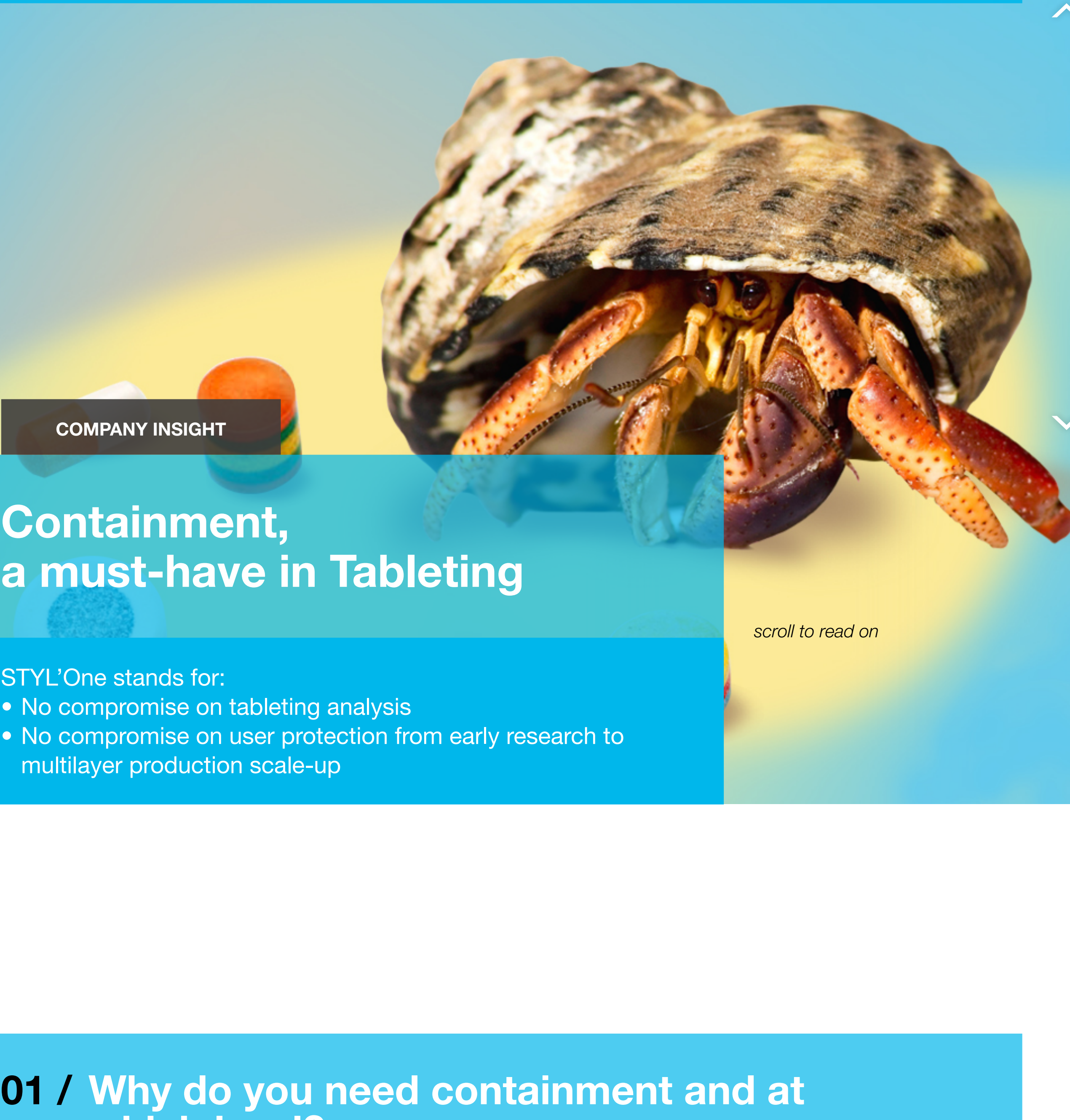




Containment, a must-have in Tableting

STYL'One stands for:

- No compromise on tableting analysis
- No compromise on user protection from early research to multilayer production scale-up

01 / Why do you need containment and at which level?

Containment is a global trend. The principle « better safe than sorry » is now the applied rule which was generated by several factors.

The number one factor is the Labour Protection Law.

An increase in safety rules and regulations for the workforce imposes the strict control of operator exposure.

Secondly with the increase of product efficiency and powders being more and more active, a higher level of protection has become necessary to ensure operator safety.

Finally with the advance of science we are more aware of risks created by active materials and more cautious about unknown active products.



02 / What is the trade-off between containment and ergonomics?

Most containment systems are cumbersome and increase the time necessary for experiments considerably. Tableting equipment is no exception. Luckily the market has created solutions and procedures which allow a safe usage of tablet presses. Even though tablet presses deal with powder in a loose state, the outcome itself, the tablet, is less prone to release loose particles in the ambient. Still it is the laboratory

manager's task to choose an appropriate level of containment and protection for the user of the compression equipment.

Medelpharm has developed a series of different solutions to fit all needs ranging from basic operator protection to the utmost fully contained compression study solution.

“ ALL MEDELPHARM EQUIPMENT IS MADE WITH CONTAINMENT IN MIND AND DESIGNED FOR MINIMISING THE RISK FROM DAY ONE. ”

03 / How are Medelpharm Tableting Instruments designed for containment?

All Medelpharm equipment is made with containment in mind and designed for minimising the risk from day one. Medelpharm uses a pragmatic approach by letting you choose the level of protection necessary and consequently offering you the best solution right from the beginning.

The equipment is made to give you the highest level of information about your tablets with a minimum amount of powder and this way is lowering the global exposure level since only a few grams of active ingredients are in the equipment at a time.

The running of the machine does not generate excess airborne particles that are potentially harmful.

Several vacuum systems keep the compression zone as clean as possible and the standard STYL'One tableting instrument runs with negative pressure in standard mode.

Our tablet presses, being easily dismantled and cleaned, guarantee that loose particles are easily washed away. All parts can be cleaned in a dish washer, and the interior of the machine can be wetted before cleaning. A short dismantling time also results in a shorter exposure and consequently minimal risk for the operator safety during the cleaning phase.

STYL'One tableting instruments are designed for protecting your team.

04 / Is Enhanced Operator Safety enough for me?

In order to better protect your operator beyond our standard design, we have created a simple but effective solution to increase the operator safety while keeping the ergonomic impact to a minimum and still remain an affordable solution.

We equipped the STYL'One with silicon seals to limit the loss and intake of air. The pressure locks from the doors ensure the fitting of the seals. Using the gloves in the back allows you to manipulate powder while remaining protected. The tablets will be released into tri-clamp-connected vessels of your choice.

You can then carry the tablets safely to other benches for physical measurements.

The air inlet/outlet is filtered with a HEPA cartridge system to prevent

pollution coming into your equipment or API involuntarily escaping the compression zone into the atmosphere.

A simple and efficient dual system allows you to adapt airflow to your vacuum system, either centralised or portable.

Optional equipment, like flexible isolators, connected to tri-clamps allow the operator to recuperate tablets in a contained environment for further analysis.

Before breaking containment, a spray gun can freeze all dust particles on the wall and floor of the tablet press. Using protective gowning, your cleaning team can finish the decontamination of the machine safely and prepare it for the next set of measurement.

“ AT THE END OF THE EXPERIMENT, THE WHOLE WORK SPACE INCLUDING PRESS AND MEASURING EQUIPMENT CAN BE WASHED DOWN WITH SPRAY GUNS, AND DRIED WITHOUT BREAKING THE CONTAINMENT. ”

05 / What if I need a fully contained R&D zone for my experiment?

If you are ready for the most exigent containment solution, you can have your STYL'One equipped with an all-inclusive glove box with R&D equipment and cleaning station sharing the same contained/ isolated zone.

The concept is quite different: The R&D press is fully running inside the isolator which is a contained R&D space of its own. The STYL'One is operated through glove ports, at the same time tablets already produced can be weighed and measured inside the isolator.

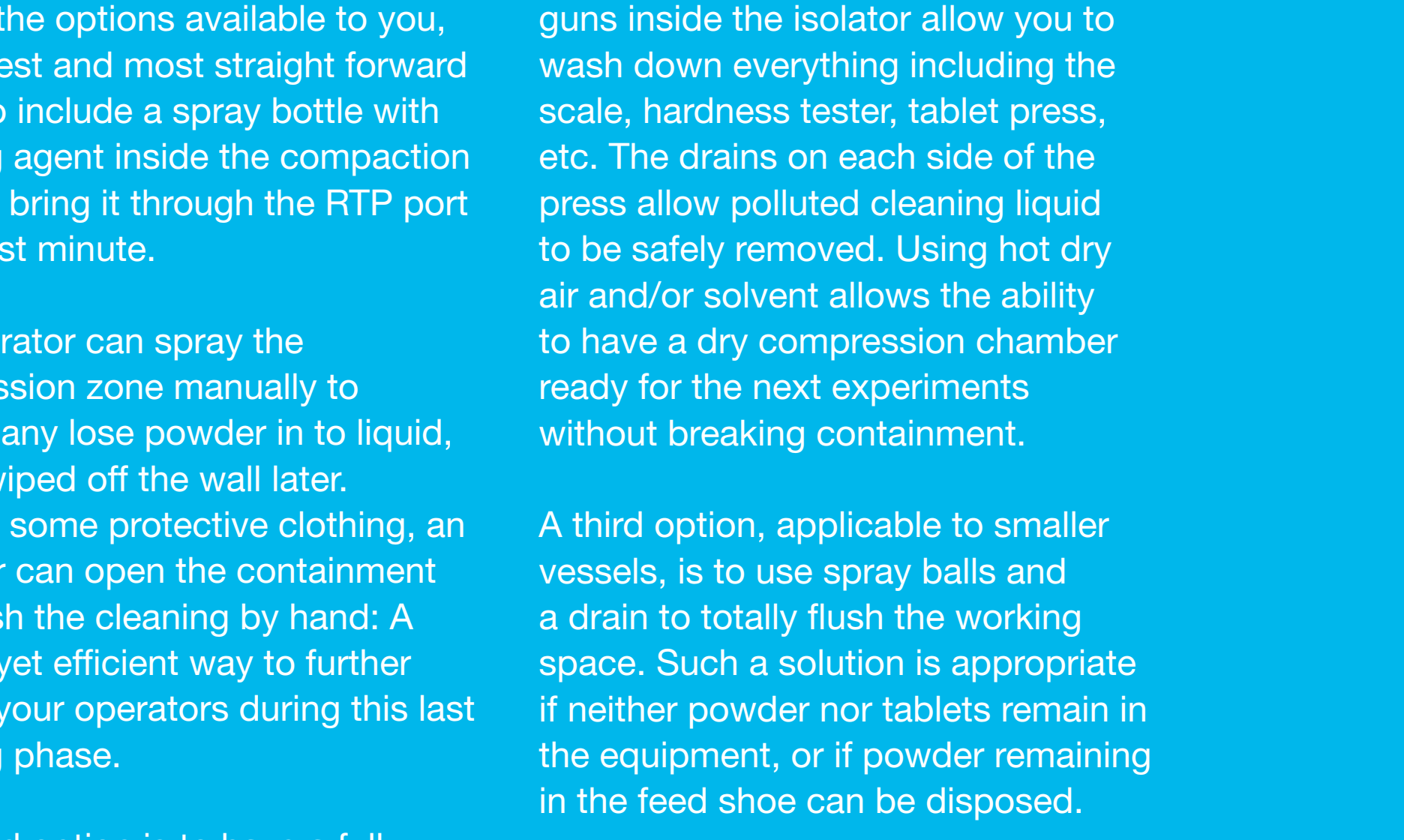
Tools which have not been used or have been dismantled, can be cleaned in an inside cleaning station.

At the end of the experiment, the whole work space including press and measuring equipment can be washed down with spray guns, and dried without breaking the containment.

All products and accessories can be moved through an RTP port to ensure safety at all times. This utmost usage of the tablet press containment requires you to operate through four pairs of gloves fitted in the front and in the back of the equipment.

Should you not wish to use containment, you can always use the research press with the large glass panels open and run the STYL'One safely according to the latest CE directives. The vacuum, scales and hardness tester are also in operation inside the containment space, sending the data straight into the central database along with the data acquired during tableting.

A very flexible and complete solution for the most demanding laboratories.



06 / What are the options for Wet/Wash/Clean in place?

Cleaning a space polluted by active ingredients has always been the frontier of containment: What do you do when you open the door?

Among the options available to you, the easiest and most straight forward one is to include a spray bottle with cleaning agent inside the compaction zone, or bring it through the RTP port at the last minute.

The operator can spray the compression zone manually to capture any loose powder in to liquid, to be swiped off the wall later. Wearing some protective clothing, an operator can open the containment and finish the cleaning by hand: A simple, yet efficient way to further protect your operators during this last cleaning phase.

A second option is to have a fully on site washable solution. After

experiments are performed, the press can be dismantled and parts cleaned inside the isolator. Alternatively the parts can be evacuated through an RTP port for cleaning. The spray guns inside the isolator allow you to wash down everything including the scale, hardness tester, tablet press, etc. The drains on each side of the press allow polluted cleaning liquid to be safely removed. Using hot dry air and/or solvent allows the ability to have a dry compression chamber ready for the next experiments without breaking containment.

A third option, applicable to smaller vessels, is to use spray balls and a drain to totally flush the working space. Such a solution is appropriate if neither powder nor tablets remain in the equipment, or if powder remaining in the feed shoe can be disposed.

“ BY FLOODING THE MACHINE WITH NITROGEN, ONE REMOVES OXYGEN AND PREVENTS OXIDIZATION OF POWDER USED IN TABLET PRODUCTION AND OF THE TABLET ITSELF. ”

06 / Flooding with Nitrogen for food products or explosives?

Another use of air tightness and cleanliness is for production purposes in the food environment.

By flooding the machine with Nitrogen, one removes oxygen and prevents oxidization of powder used in tablet production and of the tablet itself. Once produced, these prototype tablets are packed into airtight packages, still under Nitrogen environment, to be opened by the final end user.

Small controlled leaks of nitrogen can be acceptable in a workspace.

Preventing air exchange between the compression zone and the atmosphere means it can rapidly reach a low oxygen level and maintain it while leaking little Nitrogen in the environment.

Another application of containment where the compression zone is flooded with Nitrogen and the electrical cabinet in overpressure, is to ensure protection in risk explosive ATEX classified environment.

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