Directions for Use

STEAM **maxill u·test self-contained biological indicators (SCBI)**

1. maxill u·test self-contained biological indicators (SCBI)

Product code	Quantity/ pack	Pop.	Sterilization process Steam	Colour of cap	Colour change of							Incubation temperature	Biological indicator spores	Incubation Time
					Outside Type 1 Indicators on label		Type 5 Indicator inside BI PLUS			Growth media in SCBIs after sterilization and incubation				
					before	after	before	after						
					Sterilization									
								Pass	Fail	Sterile	Non-sterile			
81150	50	10^5	121°C 132-137°C	Light blue	Blue	Brown				Purple	Yellow	55-60°C	*G. stearo-thermophilus*	24 hours
81151	10		132-137°C	Light orange			Yellow	Black	Yellow-Brown					24 hours CI Instant

Application

The **maxill u·test** self-contained biological indicators (SCBI) are used for validation and routine monitoring of steam sterilization. After sterilization the SCBIs can be incubated by the user without using an external microbiological laboratory.

The **maxill u·test** SCBIs can be used for routine monitoring inside a package, container or inside a Process Challenge Device without losing sensitivity. They have been designed with a minimal internal volume.

Product description

The **maxill u·test** SCBI is designed using a plastic vial with a small internal volume containing a biological indicator spore plate and a glass ampoule with a growth medium and pH-indicator inside. For steam-process, filter paper is used as a carrier and as a barrier below the cap.

The labels of all SCBIs for steam sterilization processes contain a type 1 chemical indicator according to EN ISO 11140:2014 to check if the SCBI has undergone a sterilization process. The self-adhesive label may be detached from the SCBI and adhered on a documentation sheet.

Additionally the **u·test BI PLUS** SCBI contains a type 5 chemical indicator that can be instantly evaluated at the end of the sterilization process.

Performance characteristics

Self-contained biological indicators:

All **maxill u·test** biological indicators comply with the standard EN ISO 11138:2017.

The incubation time of **maxill u·test** SCBIs is 24 hours.

The **maxill u·test** SCBIs meet the performance characteristics published in the current United States Pharmacopeia (USP) and European Pharmacopeia (EP).

The **u·test BI PLUS** also contains a type 5 chemical indicator according to EN ISO 11140:2014. The indicator enables the user to interpret the chemical result immediately at the end of the process.

Handling Information for maxill u·test SCBIs being used individually for routine monitoring

1. Place the test vials in the most difficult location (e. g. packs or containers) and run the sterilization process.
2. After sterilization remove the vials from the package and cool them down for 15 minutes at room temperature.
3. Observe the chemical indicator strip. Colour change indicates the ampoule has be processed in a sterilizer but sterility is not for certain. If the chemical indicator on the ampoule has not changed colour, either the ampoule was exchanged by accident or the sterilizer had a failure. To ensure sterilization has occurred, the ampoule must be activated and incubated.
4. For **u·test BI PLUS** check the chemical type 5 indicator inside of the vial:
   - If all three bars have turned black the sterilization process has been successful.

   

   - If the bars remain yellow or brown and have not turned to black completely, it indicates a potential failure of the sterilization process.
5. Let the SCBI cool down. Activate the self-contained biological indicators with the crusher in the incubator by inserting the ampoule and pushing it in a sideways direction until the interior glass ampoule is broken. Do not crush the glass ampoule until the vial is at room temperature. Hot glass ampoules may burst the plastic vial.
6. Additionally mark, activate and incubate a non sterilized ampoule (positive control).
7. After activation incubate the vials together with the non-sterilized SCBI with the cap upwards at a temperature of 55ºC-60ºC.
8. Observation of growth:
   If no colour change occurs in the sterilized SCBI the sterilization process has been successful. Any change in colour of the vials coming out from the sterilizer is indicative for living organisms demonstrating non-successful sterilization processes. A longer incubation time does not increase the probability of sterility. If the vials are incubated longer than mentioned above the liquid could dry out. However the colour of the remaining crystals is still observable. It is advised to incubate the ampoules no more than 5 days and storage for documentation purposes is not needed.
9. For u-test BI PLUS

   The black colour of the type 5 indicator inside the SCBI may get a slightly less contrast after incubation. This does not change the result shown directly after sterilization.
   It may be possible that the type 5 chemical indicator (CI) inside the vial shows a fail, but after incubation the biological indicator (BI) shows a pass. This may happen, because the CI is more critical in detecting non-condensable gasses inside the vial than the BI. Depending on the load configuration, solid loads can be released without risks, but hollow devices bear a risk if the air removal inside is not sufficient and they are non-sterile inside the lumens.
10. The previously marked positive control shall change colour demonstrating growth after one day incubation time. If this test does not show colour change, the incubator has not been switched on or the whole test has to be repeated with a new biological indicator batch.
11. Keep records of the results. Include time, date and batch number of the sterilization cycle, time and date of the incubation start and incubation duration with a result. Include a name and signature of the person responsible.
12. If any of the sterilized test vials show color change the sterilization process was not successful, check the sterilizer for malfunctions.

Storage and Disposal

1. For longer periods store all **maxill u·test** SCBIs in the original package between 5°C - 30°C.
2. The vapour of chemicals especially hydrogen peroxide may change the chemical indicator on the label before or after sterilization. Therefore do not store them together with other chemicals.
3. The indicators should not be used after expiry date. Sterilized vials may be disposed with normal waste.

Safety Precautions

1. Do not crush the glass ampoules until the vial is at room temperature! Hot glass ampoules may burst the plastic vial.
2. SCBI must not be used in dry heat sterilization processes. Glass ampoules and plastic vial may explode or melt.
3. In small sterilizers steam is generated inside the sterilization chamber. The walls and the bottom may heat up above 180°C if there is not enough water inside. Therefore the test device should not be placed at the bottom or close to the walls in those sterilizers to prevent melting of the outside plastic case or plastic vial.

For further technical details please contact **maxill.**

maxill inc. 80 Elm Street, St. Thomas, ON, N5R 6C8 Canada
Toll Free: 1-800-268-8633 **Fax:** 519-631-3388 **www.maxill.com**

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Certificate of Analysis for
maxill u·test Steam Self-Contained Biological Indicator

These self-contained biological indicators (SCBI) contain carriers inoculated with ***Geobacillus stearothermophilus***[1] and an ampoule filled with bacterial culture medium to monitor steam sterilization processes.

Performance Data for Lot: **Expiry Date:**

Organism *Geobacillus stearothermophilus*[1]

Mean Strip Recovery	**[CFU]/carrier**	Colony Forming Units/carrier
D $_{121°C\ Steam}$ **Value**	**[min]**	Tested using survival curve and survival-, kill window with following test conditions: water 121°C on paper
z $_{Steam}$ **Value**	**[°C]**	tested at 118°C, 121°C, 124°C
$F_{BIO121°C}$ Value	**[min]**	Log population x D-value; Sterilization time to reach 10^0 CFU

This document certifies that the Biological Indicators for this lot meet **maxill's** Quality Control Specifications and performance parameters published in the current United States Pharmacopeia (USP) and the EN ISO 11138:2017 standards. The above indicated specifications are tested in regular intervals until the expiry date is reached. The continuous quality is guaranteed by the **maxill** quality management system according to EN ISO 13485:2016.

Date: _____

Tested for maxill

Paul E Shaw

Approved by
Paul Shaw
maxill inc.