



Date: 17 May 2017

URGENT FIELD SAFETY NOTICE

Commercial name of the product: 4.5" Brennen® Skin Graft Mesher
Codes: 131500, 131501, 131502, 131503, 131504, 131506
Type of action: New Cleaning and Sterilization Instructions
Attention: Sterilization Services

Dear Customer,

At Mölnlycke, patient safety is our highest priority. You were notified of a Field Safety Corrective Action recently and asked to cease use of your 4.5" Brennen® Skin Graft Mesher. We have completed our validation activities and are now able to provide you with new Sterilization Instructions for the 4.5" (11.43 centimeters) devices. *These instructions do not apply to the 6.5" Brennen Skin Graft Mesher.* We have also updated our Automated and Manual Cleaning Instructions that will allow you to resume use of your Brennen Skin Graft Mesher. Please utilize the instructions below for all cleaning and sterilization activities for the 4.5" Brennen Skin Graft Mesher.

Please be advised that the **4.5" Brennen Skin Graft Meshers** are subject to this notification, including devices sold by Mölnlycke and by Stellen Medical (previously known as Brennen Medical).

Disassembly is required for both automated wash and manual wash processes.

1. Detach rear plate comb by loosening thumb screws.
2. Pull rear comb up and back to remove.
3. Detach face plate by removing the three screws using a phillips screwdriver.
4. Detach the stainless steel weighted base using the hex wrench.

Automated Wash

Pre-rinsing under cool running water is recommended prior to the following cycle:

Phase	Recirculation time (minutes)	Temperature	Detergent type and concentration
Pre-wash 1	2:00	Cold tap water	NA
Enzyme wash	2:00	Hot tap water	Prolystica® 2x Enzymatic 1/8 oz./gal or 3.7mL of an equivalent pH neutral enzymatic cleaner
Wash 1	2:00	65.5°C (121°F)	Prolystica® 2x Enzymatic 1/8 oz./gal or 3.7mL of an equivalent pH neutral enzymatic cleaner
Rinse 1	1:00	Hot tap water	NA
Drying	2:00	90°C (194°F)	NA
Reassembly	NA	NA	Attach stainless steel weighted base using two machine screws and a hex wrench. Attach rear plate comb by tightening two thumb screws.



Phase	Instruction	Temperature	Detergent type and concentration
Rinse	Rinse under cold running tap water to remove gross soil	Cold tap water	NA
Wipe	Wipe surfaces with disinfectant wipe	NA	Caviwipe or similar
Disinfection	Spray all surfaces with disinfectant Hold 2 minutes	Room temperature	Prolystica® 2x Enzymatic diluted 1/8 oz./gal or 3.7mL of an equivalent pH neutral enzymatic cleaner
Scrub	Scrub all surfaces, and periodically rotate rollers for a total of 3 minutes	NA	NA
Rinse	Rinse under cold running tap water	Cold tap water	NA
Dry	Dry with lint free cloth	NA	NA
Reassembly	NA	NA	Attach stainless steel weighted base using two machine screws and a hex wrench. Attach rear plate comb by tightening two thumb screws.

Sterilization Instructions

Step	Description	Required Accessories
1	Packaging Wrap mesher, face plate and screws in two layers of sterilization wrap.	Sterilization wrap (extra heavy due to components' weight)
2	Sterilization Warning! Ensure that the sterilizer's maximum load is not exceeded. Steam sterilization is the recommended method of sterilization. There are no contraindications for sterilizing the Brennen Skin Graft Mesher with following parameters: Pre-vacuum 4 pulses T° : 134°C (273°F) Holding Time : 4 minutes minimum Cool the double wrapped sterilized components at room temperature for a minimum of 50 minutes	High-speed pre-vacuum steam sterilizer

What you need to do

1. Please ensure that these instructions are communicated to the individuals within your facility that are utilizing and processing the 4.5" Brennen Skin Graft Meshers. Do not process the Brennen Skin Graft Meshers with other cleaning and sterilization instructions.
2. Please remove the tag "FSN2017-03(03)" from the devices and destroy it.
3. We have provided both the Automated Wash and the Manual Wash instructions. Please utilize the cycle which is most appropriate for your facility. Performing both cycles is not required.
4. If you have forwarded any affected devices to other healthcare institutions, please send them a copy of this Field Safety Notice Update immediately upon receipt of this letter.
5. If you are a distributor, please inform your customers by sending them a copy of this Field Safety Notice Update.



Please continue to follow the reporting procedures established by your facility should you need to report any issues.

Any questions?

Please contact your local Mölnlycke Customer Service or Account Manager if you have any questions or concerns regarding this Field Safety Notification. You may also contact:

Vigilance: Linda Magnusson (vigilance@molnlycke.com) or +46 31 352 3733

Thank you for your time and attention. Mölnlycke apologizes for any inconvenience this action has caused. Again, patient safety is at the front of all we do at Mölnlycke. We are confident that this updated information allows proper and safe usage of the 4.5" Brennen Skin Graft Meshers.

Sincerely,

