

L110 Hydrophilic coating

L110 is a hydrophilic coating with superior lubricating properties, which can be applied to most surfaces and materials. L110 can be used for a number of applications but is developed for single use medical devices.

L110 Coating features

- Very lubricating when wetted with water (low friction)
- Very long in-use lubrication (high durability)
- Long functional life easily supporting a 2 year shelf life of the coated medical device
- For stability L110 come in two bottles:
 - The coating liquid L110-A
 - The thermal crosslinking activator L110-B in powder form
- Fast, simple and flexible coating process
 - Dip in solution - Let excess drip off - Dry
- Excellent adhesion to most materials
- Biocompatible
- Water based chemistry
- FDA approved ingredients

Important notes on the use of L110

- It is critical to ensure a clean and compatible surface for L110 to adhere to, otherwise the adhesion of the coating may fail without notice.
- The mixed coating liquid can be used for coating for a limited time (days). Extended use will give less crosslinked coatings with lower durability.
- It is critical to dry/cure the coating for at least one hour at 70°C. Shorter drying time or lower temperature will give less crosslinked coatings with lower durability.
- It is very important to dry the coating slowly, to ensure proper crosslinking. This is best achieved by having a high humidity (40%-60% @ 70°C) in the drying oven.
- While most of the crosslinking occur during drying/curing, some crosslinking will occur in the following days. Thus, testing of the coating properties should not be done until 7 days after coating.

Functional life of an L110 coating

An accelerated functional life study (ASTM-F1980) has been made in normal air. No degradation can be measured over the effective 6 years of the study. If stored as recommended a device with an L110 coating will stay lubricating for many years, and the hydrophilic coating thus easily support a 2 year product shelf life.

Evaluating the coating on your device

When you have coated your device, it is important to evaluate the lubricating performance of the coating to assess the suitability for your application. There are three characteristics of a hydrophilic coating:

- **Activation time.** How long time is required submerged in water for the coating to become highly lubricating?
- **Lubricity.** What is the friction of the coated device?
- **Durability.** How long does the coating remain lubricating while in-use?

Unfortunately, no standard is established for testing these coating characteristics, but three common methods exist.

1. **Automated testing.** A small flat rubber pad is pressed against the coated surface at a controlled force. The pad is moved back and forth over the surface while measuring the friction force. Activation time, lubricity and durability is calculated from the friction force vs. number of passes movements.
2. **Finger testing.** Similar to the automated testing but using a finger instead of the rubber pad. This method is not very comparative or reproducible, but it is easy to do and with experience it can be very good when comparing two coatings on the same device.
3. **Device and application specific testing.** These test methods often consist of a model of the body part where the device will function, and a procedure for using the device while assessing the coating performance.

Due to the lack of established standards it is more than difficult to compare performance of lubricating coatings across sites, coated devices, test systems. Direct comparison is only possible when you have devices coated with two different coatings, tested at the same place and time on the same test equipment.

Activation time

Low friction is first obtained when the coating has absorbed enough water and swelled into a hydrogel. This activation time is measured from the time the coated device is submerged in water until it obtains low friction. For low crosslinked coatings the activation time is up to 3 seconds. For thick and very crosslinked coatings the activation time can be up to one minute. For L110 the activation time is in most cases 5-15 seconds.

Lubricity

Following activation, the coating friction will remain low for a long time. The friction is often so low that it is not relevant to measure the friction coefficient or friction force.

Durability

Friction will remain low for some time and then it will increase when the coating is worn down. The time until friction increases depends on the characteristics and thickness of the coating, the device geometry, contact force & area, the speed of movement, temperature, contact with abrading surfaces etc.

The coating durability is limited by two mechanisms:

1. **Wear.** How fast the coating is worn during use.
2. **Adhesion failure.** If the coating does not adhere well to the device then the friction force may be enough to pull the coating off the device.

Processing guidelines

L110 preparation prior to coating

To ensure stability L110 is supplied in two bottles L110-A (hydrophilic coating liquid) and L110-B (activator/crosslinker). Shortly before use the coating liquid should be mixed as follows:

1. Fill the L110-B bottle with pure water. Replace the lid and invert the bottle repeatedly to ensure complete dissolution of the thermal activator. Using warm water and leaving a little air in the bottle will speed up dissolution.
2. Transfer the liquid content of the L110-B bottle to the L110-A bottle. Replace the lid and invert the bottle a least 20 times to ensure uniformity of the coating liquid.

The L110 coating liquid is now activated and is ready for use. Optionally, the L110-B activation powder can be added directly to the L110-A liquid, but full dissolution and full uniformity must be ensured.

Surface preparation

The surface to be coated with L110 should be clean and free of dust, oil, water and volatiles. Please note that a single molecule thick layer of oil or mould release agent is enough to cause poor coating adhesion. To ensure good adhesion we strongly recommend an oxygen plasma treatment shortly before coating or cleaning the surface with an alcohol wetted swap.

Coating methods

L110 is best applied by dip coating followed by slow (1-2 mm/s) extraction from the coating liquid. The slow extraction is to ensure good uniformity of the coating. Excess coating liquid should be given time to drip off the device. Alternatively, a swap can be used to remove excess from the lower parts of the device.

Drying and crosslinking

While still wet the device should be placed in a drying oven set at 70°C. The coating will simultaneously dry and crosslink at the elevated temperature. The thermal curing must be at least one hour at 70°C but can be significantly longer without causing any degradation. If 70°C is higher than what is permitted by the device materials, a lower curing temperature can be used, but for each 10°C lower curing temperature the minimum curing time must be increased by a factor of three. Too fast drying will result in an under-crosslinked coating, this is best avoided by ensuring 40%-60% relative humidity in the drying oven. Fast drying is not good.

Device orientation

Elongated devices should be dip coated and dried in a vertical orientation.

Coating thickness

The optimum coating thickness depend on the use of the medical device. The thickness should be adjusted for optimum lubrication and functional duration time.

Thickness is easiest adjusted by diluting the L110 solution with pure water. Dilution will reduce the coating thickness but will not negatively affect the properties of the coating.

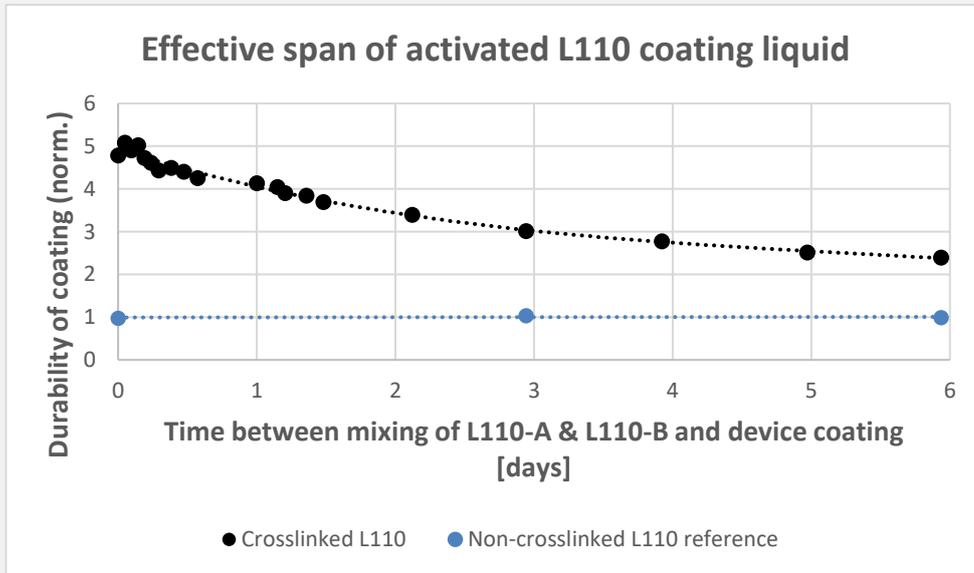
L110 in the coating tank

The coating tank where the L110 coating liquid is kept should be made of inert materials such as glass, polished stainless steel, polypropylene etc. Other materials may be corroded by the activated coating liquid.

Fill the coating liquid into the coating tank and keep it static without automated agitation or filtering. The coating liquid will not sediment over a production day, but at the start of each production day is it recommended to stir the coating liquid to ensure uniformity. For this stirring use a hand operated paddle, don't use high shear machine stirring as this may degrade the coating liquid.

Useful time of activated L110 Coating liquid

When the L110-B activator is dissolved it starts to decay, and thus the concentration of crosslink activator will decrease over time. Crosslinking and thus durability of the L110 coating depends on the concentration of crosslink activator in the coating liquid. Once activated the L110 coating liquid thus have a limited active life.



Coating durability versus the time since the coating liquid was activated.

While the activated coating liquid degrade over time, the crosslinked coating on devices remain stable for years.

When first mixed the L110 coating liquid give coatings with excellent durability, but for single use devices half the initial durability is likely more than enough. Therefore, for most devices we believe the activated L110 coating liquid can be used for 5 days after activation. However, it is the responsibility of the medical device manufacturer to test and document this to ensure proper coating performance on their device.

To maximize the useful time of the L110 coating liquid we recommend maintaining a low temperature in the coating tank. 18°C-20°C is good and it should never exceed 25°C.

L110 Re-activation

To ensure a consistent high-quality coating we recommend discarding the activated coating liquid after 5 days (or shorter if this is suitable for your device). For some devices and coating processes it may be possible to re-activate the coating liquid by adding an extra bottle of activator. However, we do not recommend this nor guarantee coating performance, and this should be done with caution as the coating quality may diminish without this being visible.

Stop coating and discard the coating liquid immediately if:

1. Lumps, gel or crust is visible in the coating liquid.
2. Coating on the device appear non-uniform.
3. The lubricating performance or thickness of the coating is out-of-spec.

To ensure consistent device quality the manufacturer of a medical device has the full responsibility for proving and documenting coating performance when re-activation of L110 is used.

Storage, disposal and safety

Storage

L110-A Liquid coating solution

Store L110-A upright and in tightly closed containers in a cool, dry environment away from direct sunlight at a temperature of 4-27°C (40-80°F).

L110-B Thermal crosslinking powder

Store L110-B upright and in tightly closed containers in a cool, dry environment away from direct sunlight at a temperature of 4-22°C (40-80°F).

Shelf life is 12 months from date of manufacture.

Dry L110 coating

A device with an L110 coating should be stored at normal room temperature in dry air. The device with the L110 coating should be stored so it is not exposed to;

- Temperatures above 70°C (5 minutes exposure to 100°C is acceptable)
- Liquids or condensing atmosphere
- High doses or prolonged exposure to UV- or gamma radiation
- Abrasion

Disposal

L110 may be included with other similar waste to be discarded for destruction or reclaim in accordance with local state and federal regulations. It is the responsibility of the customer to ensure the disposal of L110 and residues are made in observance of all local environmental regulations.

Environmental, Health and Safety

L110-A Liquid coating solution

L110-A solution is mainly water with hydrophilic polymer and a plasticizer. The solution poses little chemical risk. The solution is slippery when wet and sticky when drying, handle with care to avoid slipping or falling.

L110-B Thermal crosslinking powder and Mixed L110 (A+B) solution

Wear chemical goggles, chemical gloves and suitable protective clothing. Do not get into eyes, or onto skin or clothing. Use with adequate ventilation to avoid breathing powder. In case of contact with skin, wash affected area with soap and water. In case of contact with eyes, rinse immediately with water and flush for 15 minutes lifting eyelids frequently. Get emergency medical assistance.

Dry L110 coating

When dried the L110 coating is biocompatible and completely safe. No precautions are needed, but we don't recommend getting L110 dust into the eyes or consuming it.

Warranty

The information in this datasheet is based on our experience and is, we believe to be reliable, but may not be complete. We make no guarantee or warranty, expressed or implied, regarding the information, use, handling, storage, or possession of this product, or the application of any process described herein or the results desired, since the conditions of use and handling of the product is beyond our control.