

# L120 Hydrophilic coating

L120 is a hydrophilic coating with superior lubricating properties, which can be applied to most surfaces and materials. L120 can be used for a number of applications but is developed for single use medical devices made of thermoplastic elastomers.

## L120 Coating features

- Very lubricating when wetted with water (low friction)
- Very long in-use lubrication (high durability)
- Excellent adhesion to polyurethane, PVC and most TPE's
- Long functional life easily supporting a 2 year shelf life of the coated medical device
- Fast, simple and flexible coating process
  - Dip in solution - Let excess drip off - Dry
- No UV/thermal curing or crosslinking step is required
- Biocompatible
- FDA approved ingredients

## Important notes on the use of L120

- It is critical to ensure a clean and compatible surface for L120 to adhere to, otherwise the adhesion of the coating may fail without notice.
- The coating dries in minutes at room temperature. To avoid smell of residual solvent it is recommended to dry the coating overnight in a well ventilated location, or for one hour at 50°C.

## Functional life of an L120 coating

An accelerated functional life study (ASTM-F1980) has been made in normal air. No degradation can be measured over the effective 4 years of the study. If stored as recommended a device with an L120 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 pas 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 cured/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 L120 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

### Surface preparation

The surface to be coated with L120 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

L120 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

L120 will dry at room temperature in minutes, but residual solvent will smell if the coating is not dried enough. The drying can be accelerated at 50°C for 1-2 hours. Drying longer will not cause any degradation of the coating. Ensure proper ventilation to remove evaporated solvent.

### 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 L120 solution a little with pure isopropanol. Dilution will reduce the coating thickness but will not negatively affect the properties of the coating.

### L120 in the coating tank

The coating tank where the L120 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 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.

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## Storage, disposal and safety

### Storage

#### Liquid L120 coating

Store L120 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). Shelf life is 24 months from date of manufacture.

#### Dry L120 coating

A device with an L120 coating should be stored at normal room temperature in dry air.

The device with the L120 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
- Oil, grease, fingerprints etc.

### Disposal

L120 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 L120 and residues are made in observance of all local environmental regulations.

### Environmental, Health and Safety

#### L120 Liquid coating solution

L120 solution is solvent with hydrophilic polymer. The solution poses little chemical risk but avoid breathing vapors and contact with the body. The solution is slippery when wet and sticky when drying, handle with care to avoid slipping or falling.

#### Dry L120 coating

When dried the L120 coating is biocompatible and completely safe. No precautions are needed, but we don't recommend getting L120 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.