

FREQUENTLY ASKED QUESTIONS

NOVUQARE ROTARY SEALERS

SEALMATE

FAQ's

1. Where are Rotary Sealers used ?

Medical sealers are used in hospitals and clinics, in so called Central Sterilisation Service Departments (CSSD's). Prior to instruments being sterilised in so called autoclaves (sterilisation "ovens"), the instruments are packaged in a special manner.

There are different types of autoclaves: steam, gas and radiation being the most typical agents being used. One packaging option is to use so called pouches (bags). These pouches are filled with instruments and sealed before going into the autoclave.

An alternative packaging option other than sealing is wrapping, whereby large sheets of special cloth are wrapped around a tray or net filled with instruments, prior to being sterilised. Hospitals use these trays a lot, because the instrument set in the tray contains all the instruments needed for one particular procedure. However, with stringent processes being in place across various hospitals; more & more hospitals are buying Rotary Sealers.

2. What type of Pouch materials are used with Rotary Sealers ?

There are different types of pouch material: paper-laminate film, Tyvek-laminate film, non-woven- Laminate film, Gusseted laminate-film and a variety in thickness. Some materials are rigid (paper), others flabby (non-woven), rough (paper), or smooth (Tyvek). The seal-making principle is always a laminate built up of several layers. While being heated, the contact layer melts and connects the laminate to the backing material.

Pouch materials are generally supplied on a reel (with two sides already sealed), or in pre-determined bag-format (three sides already sealed). The latter method is more convenient but somewhat more expensive than reels. Typically a pouch bag in The Netherlands costs €20-30ct for the hospital. Pouch materials are being sealed using a sealer.

3. Who are generally the suppliers of the pouch materials ?

There are different suppliers of pouch material, such as Tyvek (Dupont), CleanTex (SPS), Steriking (Wipak) and Hogy and a host of non-branded pouch material suppliers. There are also different folding mechanisms, such as gusseted (double folded) or self-sealing bags. Novuqare sealers are qualified for a range of materials. See table 1:

| Manufacturer | Description | Item # | Temperature range |
|--------------|-------------|---------|-------------------|
| DuPont | Tyvek | | 125° C |
| Hogy | | 1105 | 180° C |
| Hogy | | HM-1308 | 180° C |
| SPS | Cleantex | | 180° C |
| Wipak | Steriking | R42-3P | 180° C |
| Wipak | Steriking | R47 | 180° C |
| Wipak | Steriking | RB51-3P | 180° C |

Table 1

Pouch materials are typically supplied separately from sealer or other CSSD devices, usually through a tender process. The amounts involved in (multiyear) pouch contracts tends to be far greater than that of a sealer. Sometimes though, large pouch suppliers wants to “throw in” a sealer as a sweetener to make a pouch deal possible. This is the reason that several suppliers of large CSSD devices, such as autoclaves and washers, or pouch material suppliers want to have sealers in their product offering as well.

4. What are the types of Sealer markets ?

The low-end of the sealer market tends to be bar- or impulse sealers, mostly used for dental offices or very small medical clinics. The bulk of the sealer market are so called rotary sealers, whereby two conveyor belts “drag” a pouch through a sealer device, while the pouch material is being heated and pressure is applied to form a sterile barrier (i.e. a seal).

5. Are Rotary Sealers needs to be certified or is there any standard’s ?

Sealers are part of the sterile barrier system, as defined by the regulators, and sealing standards are set by the regulator, for example ISO-11607. However, sealers are not medical devices as defined by the European Union Medical Device Directive (MDD) or the FDA (USA). Strictly speaking, contrary to for example autoclaves, sealers are currently classified as laboratory instruments, not medical devices. As regulations tend to get stricter over time, this may change in the future.

6. Novuqare Rotary Sealers – Model SealMate regulatory certified ?.

SealMate rotary sealer are CE marked products.

7. Is there a real need for Rotary Sealers

In the CSSD, several large devices are installed, in particular a few autoclaves and a few washers. These devices represent hundreds of thousands of dollars in value, so far outstrip the value of a few sealers. Sealers, along with tables, trays, etc. represent the rest equipment needed to make the CSSD operational and meet good standards of functioning of the hospital w.r.t. Sterilization standards.

8. How many Sealers are required generally in any hospital ?

NVM has assessed the worldwide hospitals having CSSD facilities. We estimate that on average every hospital needs 2-3 sealers installed, with an expected lifetime of 5-7 years (depending on the region).

9. What are the different Market Segment for Rotary Sealers ?

The market is defined into three segments:

- Low-end market segment; with hospital prices below \$2000. These sealers are not validable, often bar- or impulse sealers from local/regional OEMs.
- Mid-end segment; (\$2500-\$3000 hospital prices). These sealers are validatable, but have no built-in printer.
- High end segment; (>\$3500 hospital prices). These sealers are validatable, and have a built-in printer. Some have network capability built in.

- Although there are important regional differences, we estimate worldwide volume is roughly distributed 1/3-1/3-1/3 between the Low-, Mid-, and High-end.

10. What are the 2 types of NVM Rotary Sealers

The new series of SealMate was introduced in 2018. It consists of two sealer types-

- Model **P20** (without built in printer) -- targeting the mid-end of the market
- Model **P40** (with built in printer) -- targeting the high-end of the market.

11. What are the existing experiences of NVM SealMate Sealers ?

Initial reception of the SealMate has been very positive and they appreciate the quality and high standards of the systems.

12. Who are the competition for NVM Sealmate Rotary Sealers

- Hawo is the benchmark supplier, the established market leader internationally.
- Entrhal, Gandus, LEF and Famos are the second tier and NHE's main competitors.
- Variety of local, mostly Asian manufacturers supply the bottom half of most local/regional markets, e.g. PMS from Turkey. These are currently not NHE's direct competitors.

13. What is the life time of Rotary Sealers

Customers tend to be satisfied with the offering from tier-1 or -2 suppliers and generally have little incentive to change supplier. Product innovation is typically slow and the effective product lifetime in the hospitals is long (certainly 5 years, up to 10 years or sometimes even older). Cost of ownership is relatively low for a hospital: the purchase price is a few thousand dollars (depending on the type/features), and maintenance cost is low (a few hundred dollars in direct materials and labour cost). NHE prescribes a service/maintenance every year or 100,000 seals, but many hospitals outside the Western markets do not stick to this.

14. The capacity of your sealer?

The capacity depends on the width of the pouch material. The conveyor belt speed can be set between 120-170mm/sec.

15. Which materials the sealer can work with (nylon, plastic, aluminium)?

The SealMate can seal nylon, plastic and aluminium materials. Depending on the type of material, the sealer settings (temperature, pressure and if needed also speed) will have to be adjusted.

16. The maximum size of the pouches can be sealed?

There is no maximum width of the pouch material that can be sealed.

17. How many colours can the integrated printer support?

Is it configured via computer or on the sealer?

The printer prints in one colour: black. The font and text is controlled via the sealer display.

18. Can you provide us with a complete sterilization process which includes the sealer and other devices?

We only supply the sealer. Pouch materials, autoclaves and other equipment can be sourced from third party suppliers.

19. How does the SealMate operates ?

Refer SealMate User's Manual (Instruction for Use) which provides complete description of the product and its operational usage.

20. Details on consumables required for Sealers ?.

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