HEALTHCARE - HCR
WHITE PAPER

High consistency silicone rubbers: Important material properties and processing criteria for healthcare applications

High consistency rubber (HCR) silicone is a versatile material with a long history of use in medical devices and other healthcare applications. Used to fabricate various articles, such as tubing, balloons, sheeting and molded parts, HCRs consist of a high molecular weight siloxane polymer combined with silica to produce a silicone that has a clay-like consistency in its uncured form.

There are several reasons why manufacturers choose HCRs to fabricate medical devices:

- **An established history of use in medical applications:** The widespread, successful use of HCRs in medical device applications gives manufacturers, both established operations and startups, confidence that their products should be able to gain regulatory approval.
- **Green strength:** The material's green strength, or the strength in its uncured form, also contributes to its value for producing medical device parts, which is required for some commonly used production processes such as extrusion.
- **Very high mechanical properties:** When compared to liquid silicone rubbers (LSRs), the high molecular weight of the polymer in HCRs combined with the reinforcing fillers allow for greater mechanical properties.
- **Cost-efficiency:** Due to their relatively low tooling cost, HCRs are an excellent material for low-volume compression or transfer molding.
- **Biocompatibility:** Qualified HCRs can be used for long-term (>29 days) implantable medical devices, as well as for short-term implantable devices or external medical applications. Depending on the specific medical application, HCRs are available with varying levels of regulatory support.

A comparison of curing systems: peroxide-catalyzed and platinum-catalyzed

Most HCRs are supplied using either peroxide-catalyzed or platinum-catalyzed cure systems. In peroxide-catalyzed systems, curing is not initiated until the HCR is exposed to heat. This translates into a very long work time (table life), which is beneficial for molding or extrusion. When using peroxide-catalyzed HCR systems, a post-curing process is often required to remove residual byproducts.

By contrast, platinum-catalyzed systems commonly consist of two components: one contains the platinum catalyst, and the other contains hydride functional cross-linkers and cure inhibitors. When combined, the HCR retains its pre-cure consistency for a limited time and can be processed without undesirable byproducts produced during curing.

The following table (Table 1) provides technical characteristics to assess when choosing between peroxide-cure and platinum-cured HCRs:

	Platinum catalyzed addition cure	Peroxide cure
Thick section cure	Yes	No
Cure	Accelerated with heat	Heat
Table life	Variable	Indefinite
By products	No	Yes (can be corrosive)
Post cure	Optional	Required
Shrinkage (approx., temp, dependent)	2-4 %	3-5 %
Susceptible to inhibition	More	Less
Supplied	Pre-catalyzed or uncatalyzed	Pre-catalyzed or uncatalyzed

TABLE 1: Performance characteristics of sought specialty silicone.

HCRs can be supplied either catalyzed, where the catalyst is already incorporated in the system, or uncatalyzed, where the catalyst is sourced separately.

It's important to understand how temperature can be used to optimize cure times based on processing needs. Many factors influence the conditions required to successfully process silicone rubber; optimizing these variables can ensure the fastest and most repeatable process possible.

The time needed for a platinum-catalyzed HCR to cure at a particular temperature can be adjusted by changes to the formulation. However, increasing or decreasing the processing temperature can also change the period of time required to achieve the desired state of cure for any given formulation.

Medical devices made with silicone material commonly use platinum-cure systems due to their versatility in production and the fact that there are no byproducts of the cure mechanism. During the curing process, platinum-catalyzed HCRs can be heat-accelerated for increased throughput.

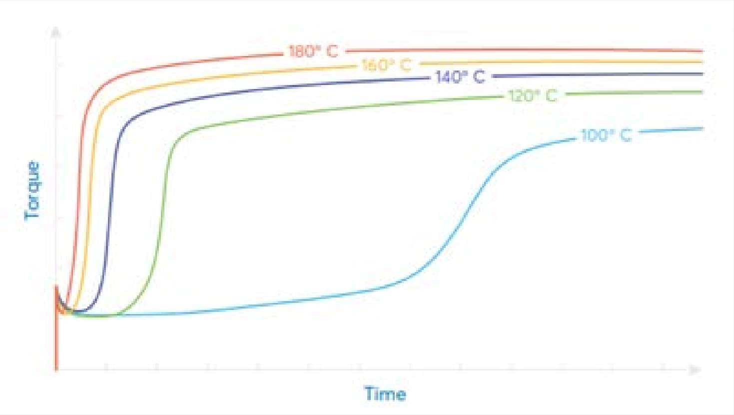


FIGURE 1: Cure profile for platinum-catalyzed HCR at various temperatures.

This graph (Fig. 1) depicts the rate of cross-linking via the force required (Torque) to deform a sample as it progressively cures over time and how changes to temperature affect the time needed to cure the silicone. There are practical limits to increasing processing temperatures to reduce cure time, so care must be taken to avoid issues such as scorch. Determining the optimal processing temperature is commonly done through experimental evaluation.

Understanding the three main HCR processing methods

There are three main methods for processing HCRs into finished components for medical devices. Device designers and manufacturers must understand these processes to optimally develop and manufacture components.

The methods are:

- **Extrusion:** For continuous profiles, such as tubing, ribbon or rod. In this process, the HCR is forced through a die to form the intended shape. It is an efficient processing method that offers design flexibility.
- **Transfer or compression molding:** Best suited for creating solid or hollow parts, such as cuffs, valves or balloons. Transfer or compression molding with HCR is often a more economical molding process for low- to medium-volume parts compared to LSR injection molding.
- **Calendering:** Creates continuous sheets for further processing (e.g.,die cutting). The sheets can be provided in either cured or uncured forms. Uncured sheeting can be used as an adhesive between two devices or components. To calender, HCRs are processed through a series of rollers that form and flatten the material into sheets with thicknesses typically ranging between 0.005 to 0.250 inches.

Once the HCR has been processed through one of these methods and the desired shape and geometry has been achieved, the material is subjected to heat to complete cross-linking and to solidify the material into the desired form.

EXTRUSION

Tubing, for catheters and other medical devices, is the most common form produced via HCR extrusion. It is also a production method for other forms, such as ribbons and rods. Some manufacturers process HCRs through extrusion systems to remove air from the silicone, screen out particulates and homogenize it for further production steps.

Parts produced through extrusion can have typical wall thicknesses ranging from less than 0.01 inches up to 3.00 inches and have a wide range of elastomeric properties, with most having a durometer in the range of 30 to 80 Type A.

Before extruding, HCRs need to be processed with a two-roll mill to soften the material, blend two parts together or add pigments or fillers. Even if a manufacturer is using a one-part, pre-catalyzed peroxide cure system, milling is still recommended for softening to aid in the consistency of processing the material, whether for extruding or molding. This processing step, as well as extrusion itself, can generate heat; if too much heat is generated, the material can begin to cure, so it is recommended for equipment to be cooled to prevent curing.

Extrusion is a steady-state process designed to continually produce a high volume of finished parts with controllable dimensions and properties (Fig. 2). Many extrusion systems use a screw mechanism to force the HCR through the die since this provides a constant material feed, which manufacturers can use to ensure uniform extrusion and control factors like wall thickness.

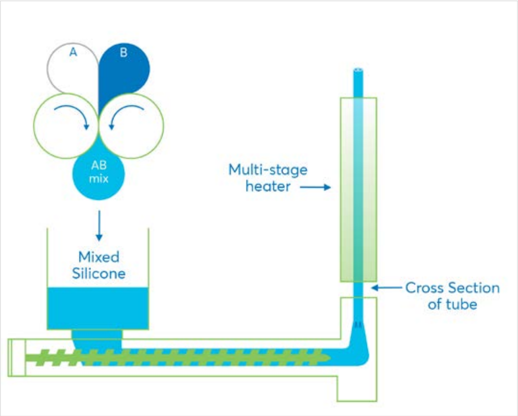


FIGURE 2: Diagram of typical extrusion system.

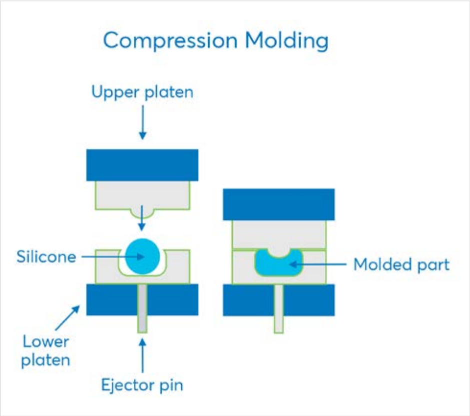


FIGURE 3: Diagram of compression molding system.

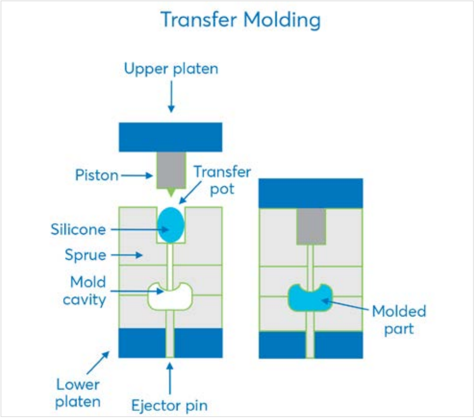


FIGURE 4: Diagram of transfer molding system.

Extrusion is an extremely efficient and relatively low-cost way to manufacture products in large volumes. While the initial systems are expensive, the die tooling is relatively inexpensive compared to other manufacturing processes. In addition, there is minimal wasted material for further savings.

After extrusion, the parts are heat cured. A variety of heating systems, including hot air or infrared ovens, can be used. Processors can adjust temperatures to control the speed of curing for both peroxide-cured and platinum-cured HCRs when necessary to manage production cycles and throughput.

COMPRESSION AND TRANSFER MOLDING

Molding with HCRs can use two types of processes: transfer molding and compression molding. Both molding methods are ideal for producing solid or hollow parts, like balloons, O-rings and gaskets. Similar to extrusion, these processes form the HCR into the desired shape while heat is applied to cure. They also typically require the same milling processes used with extrusion to blend and soften the HCR to prepare for molding.

With compression molding, the HCR is placed into the cavity of the mold, which determines the part geometry. Then the heated platens are closed, and an electric, pneumatic or hydraulic press applies force to cause the silicone to flow inside the cavity (Fig. 3). The size and shape of the preform is critical for a part to conform to dimensional specifications.

This type of fabrication is often used for prototyping and can also be useful in low-volume production. The device manufacturer must consider that where the platens come together, there will be a parting line where silicone can get pushed into, causing flash. The flash will then need to be removed, adding another step to the process.

In transfer molding, a pre-weighed HCR portion — typically called a charge — is put into a transfer pot and injected into a mold cavity (Fig. 4). After the silicone is injected into that heated cavity, it cross-links and cures upon exposure to heat. Once it's solidified in its desired shape, it can be pulled out and continue to the next process step or production cell.

Compared to HCR extrusion, compression and transfer molding are both manual processes but can be productive and cost-effective ways to produce unique shapes and parts. In rare cases, high cavitation molds can be used for high-volume compression and transfer molding.

Liquid silicone rubber can also be used in liquid injection molding processes to create molded parts and has a much faster production rate compared to these molding methods. So, for higher-volume part production, using liquid injection molding may be a better alternative.

CALENDERING

Calendering involves processing HCRs to create a flat sheet with a uniform thickness that can be used to produce a silicone sheet for further processing, such as die cutting or to apply the silicone to a substrate (such as fabric, film or foil) or to create a rubberized composite. Calendering forms and flattens the HCR into sheets with thicknesses typically ranging between 0.005 to 0.250 inches.

Calendering using HCRs offers a variety of processing options, depending on whether there is a single sheet of material being produced or if the HCR is being applied to a substrate. The calender is made up of a series of rollers that work together to apply pressure, transferring materials from roll to roll at differing speeds and directions (Fig. 5).

As with both extrusion and molding, the first step in calendering is to mill the HCR to make it ready for processing. The HCR is squeezed through adjustable gaps between the rolls. Depending on what is being produced, the manufacturer can introduce liners and carriers as well as substrates to apply the silicone to by varying the configurations of these rollers.

Calendering can apply silicone to one surface or to multiple surfaces. Some manufacturers will send material through the process multiple times, applying silicone onto a substrate, curing it and then bringing it back to apply another layer of silicone on the opposite side.

The sheeting is cured by applying heat after the calendering process is complete. It can also be left uncured, if the material will be used as an adhesive and cured onto a substrate.

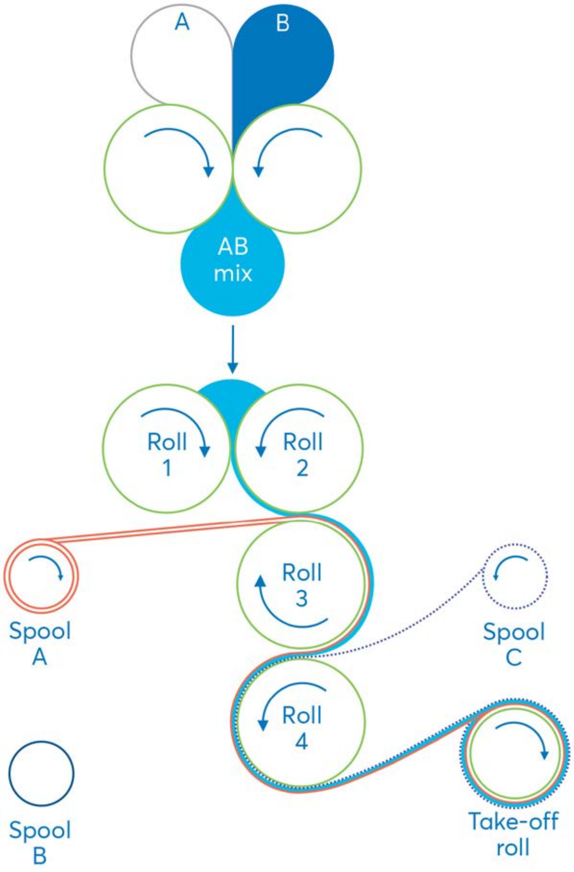
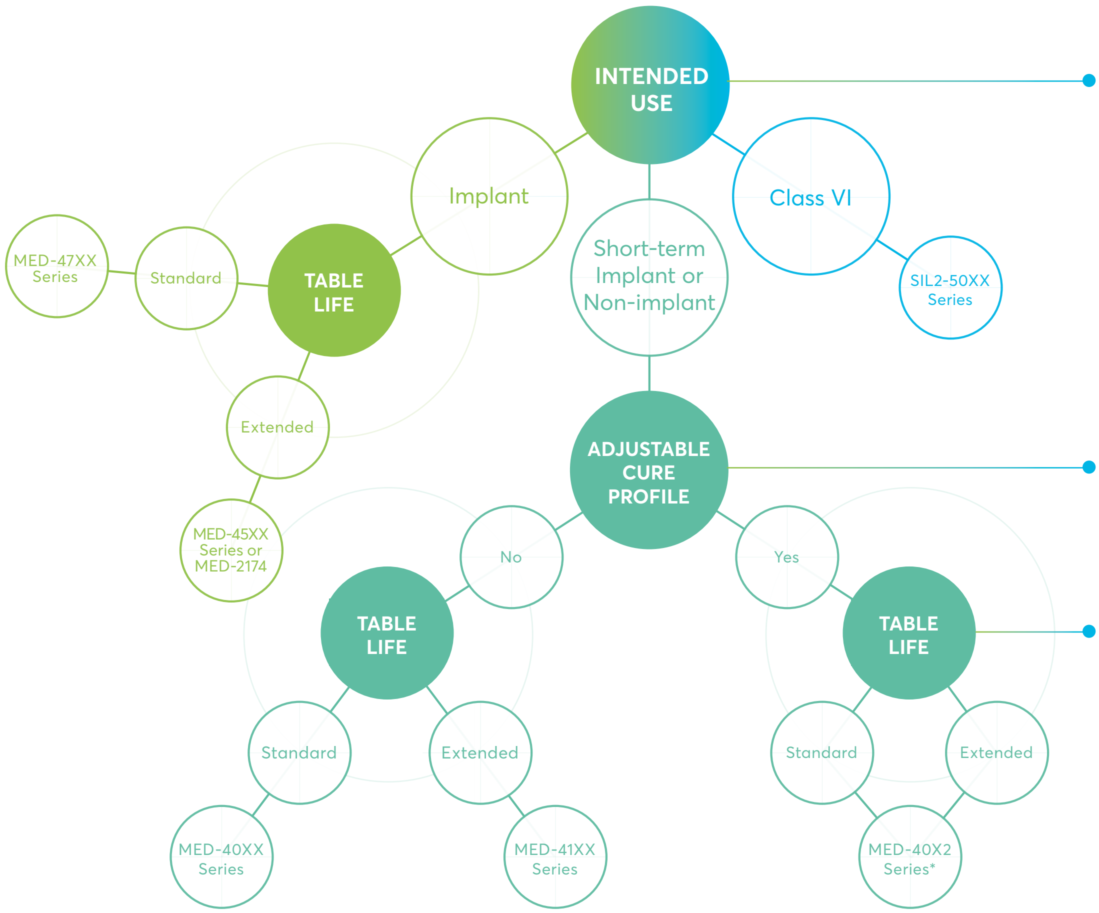


FIGURE 5: Diagram of calendering system.

There are three main methods for processing HCRs into finished components for medical devices. Device designers and manufacturers must understand these processes to optimally develop and manufacture components.

Choosing the best HCR for your application

Choosing the right HCR for your medical device application depends on factors such as intended use and table life, which are related to both the end use of the device and the manufacturing process to be used.



Intended use
Is the device an implant, external device or disposable device?

Cure profile
Do you need to control the HCR's cure rate?

Table life
Do you need the indefinite table life of a peroxide-catalyzed HCR? Or can you utilize a platinum-catalyzed HCR with a standard table life?

*Depending on whether you need standard or extended curing, MED-40X2 Series is available with either platinum or peroxide catalysts.

Contact NuSil® to get started

Choosing the right HCR for medical device manufacturing silicone has its challenges. We're ready with the insight, technical expertise and support to meet your unique needs. From prototype scale to mass production, Avantor® has the expertise, processes and proprietary technology to customize our NuSil brand HCR silicones based on your unique specifications.

To learn more, visit **avantorsciences.com/nusil/HCR** or contact NuSil experts today at **silicone@nusil.com** or **+1 (805) 684-8780**.

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