MPM Medical – Recall of Regenecare® HA Hydrogel (lidocaine)

- On December 2, 2020, MPM Medical announced a voluntary, consumer level recall of one lot of Regenecare® HA Hydrogel (lidocaine) 2% topical gel, due to contamination with *Burkholderia cepecia*.
    - Patients that have the recalled Regenecare HA Hydrogel should stop using it.
    - MPM Medical is only recalling some tubes of Regenecare HA Hydrogel. Other tubes of Regenecare HA Hydrogel and over-the-counter topical lidocaine products are available for patients to use and are not being recalled.
- The recalled lot is listed below.

Product Description	NDC#	Lot# (Expiration Date)
Regenecare HA Hydrogel (lidocaine) 2% topical gel	66977-107-03	41262 (01/2021)

- Regenecare HA Hydrogel is an over-the-counter product that contains 2% lidocaine and is used topically for temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin.
- Topical application of Regenecare HA Hydrogel contaminated with *B. cepacia* may result in local skin infections. For immunocompromised patients, including patients receiving chemotherapy and patients with cystic fibrosis, the skin infection is more likely to spread into the blood stream leading to life-threatening sepsis which includes symptoms such as fever, difficulty breathing, low blood pressure, fast heart rate, mental confusion and possibly death.
- To date, MPM Medical has not received any reports of adverse events related to this recall.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled Regenecare HA Hydrogel.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact MPM Medical at **1-800-232-5512** for further information regarding this recall.