



Form No. 01

**DOCUMENTS CONTAINING TECHNICAL SUMMARY OF THE MEDICAL EQUIPMENT**

Name and address of the establishment applying for the registration number of the medical equipment

Name: New Tac Kasei Co., Ltd.

Address: 4148 Kamitakano Toyonaka-cho, Mitoyo-city, Kagawa 769-1504, Japan

January 21, 2021

No.	Heading	Content
1	Description of medical equipment	
1.1	Description of medical equipment	The hydrocolloid pad in this product MATSUKIYO HYDROCOLLOID PAD absorbs and retains the wound fluid (exudate) released from wounds. This is then formed into a gel layer to provide an optimally moist environment for wound healing. The wound fluid (exudate) contains components that promote cell growth and regeneration, which play important roles in the wound healing process. Note: It is not unusual for the hydrocolloid pad in this product to turn whitish or exhibit swelling after it absorbs moisture. Additionally, the hydrocolloid may become white when the pad absorbs the moisture from sweat produced on the applied skin surface.
1.2	List of accessories and fittings	This product consists of an absorbent layer of hydrocolloid pad and a release liner as backing. The product is then packed into individual sterile paper packaging.
1.3	Purposes/Instruction	For the protection, maintenance of a moist environment, promotion of healing and pain relief of wounds such as minor cuts, scrapes, puncture wounds, scratches, blisters and minor burns.
1.4	Instruction	(1) Hold the opening (OPEN) of the individual package and open it gradually. Hold the product with the release liner side facing up with both hands. (2) Pull the product lightly in both directions so that the release liner can be lifted. (3) Hold the release liner without making contact with the adhesive surface. Peel off the liner slowly. (4) Position the center of the product on top of the wound, and then peel off the remaining release liner. (5) Press down the edges of the product onto the skin with your hands to ensure the whole product is securely adhered.
1.5	Contraindications	Do not reuse this product.
1.6	Warnings and cautions	<ul style="list-style-type: none"> <li>• Please read the package insert carefully before use.</li> <li>• Do not use this product on infected wounds or wounds that have already formed scab.</li> <li>• Clean the wound and its surrounding skin area thoroughly with tap water before use.</li> <li>• Select a product of a larger size than that of the wound.</li> <li>• Do not use the product if its individual packaging has been left open. Do not reuse the product.</li> <li>• Do not use for infants under 2 years of age. Parental supervision is required for usage on infants and children.</li> <li>• Patients undergoing treatment for diabetes or blood circulation disorder</li> </ul>



		<p>should seek medical advice from a doctor before using this product.</p> <ul style="list-style-type: none"> <li>• Store in a cool dry place without exposure to direct sunlight.</li> <li>• Keep out of reach of infants and children.</li> <li>• Do not use after expiration date.</li> </ul>
1.7	Possible bad effects	Depending on the wound condition and the individual constitution, scarring and/or changes in skin pigmentation may occur.
2	Information about products sold in various countries (if any)	
	Japan	
3	Instruction which has been registered in other countries (if any)	
	None.	
4	Information about the noticeable safety/operation of medical equipment products	
	None.	

We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment

*Atsushi Yokouchi*

Atsushi Yokouchi

R&D Manager

