

REPUBLIC INDONESIA
KEMENTERIAN HUKUM DAN HAK ASASI MANUSIA

SURAT PENCATATAN CIPTAAN

Dalam rangka perlindungan ciptaan di bidang ilmu pengetahuan, seni dan sastra berdasarkan Undang-Undang Nomor 28 Tahun 2014 tentang Hak Cipta, dengan ini menerangkan:

Nomor dan tanggal permohonan : EC00202321805, 17 Maret 2023

Pencipta

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Pemegang Hak Cipta

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Kewarganegaraan : Indonesia

Jenis Ciptaan : **Buku Panduan/Petunjuk**

Judul Ciptaan : **Treatment Of Burn Injury Using MSCs Secretome**

Tanggal dan tempat diumumkan untuk pertama kali di wilayah Indonesia atau di luar wilayah Indonesia : 17 Maret 2023, di Jakarta

Jangka waktu perlindungan : Berlaku selama hidup Pencipta dan terus berlangsung selama 70 (tujuh puluh) tahun setelah Pencipta meninggal dunia, dihitung mulai tanggal 1 Januari tahun berikutnya.

Nomor pencatatan : 000454728

adalah benar berdasarkan keterangan yang diberikan oleh Pemohon.

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a.n Menteri Hukum dan Hak Asasi Manusia
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| | STANDARD OPERATING PROCEDURE (SOP) | Document Num.: SOP/LB/2020 |
| | | Release date: 16 March 2023 |
| Treatment of Burn Injury using MSCs Secretome | | Effective date: 16 March 2023 |
| | | Version: 1 |
| | | First draft: THCT |
| | | Prepared by: Sukmawati T.T. |

Product:

MSCs secretome (or conditioned media) is a cell-free product harvested from umbilical cord mesenchymal stem cells culture media which contains a vast amount of growth factors, cytokines, and exosomes.

Objectives:

- Accelerates tissue regeneration of burn injury patients
- Facilitates a faster burn injury healing
- Prevents infection risk
- Prevents keloids formation

Materials / Equipment:

1. Personal protective equipment (PPE): mask, gloves, medical gown
2. Sterile dressing
3. Syringe 10 cc
4. Sterile gauze
5. Bandage
6. Stainless steel kidney dish
7. Chirurgical tweezers/surgical forceps
8. Chirurgical scissors
9. Sofra-Tulle/Tegaderm
10. 0.9% NaCl
11. ddH₂O
12. Secretome gel / serum 10% and 20% (patented)
13. Sterile cotton bud

Documents Required:

1. Patient's medical record

1. Pre-treatment Preparation

- An explanation is given to the patient/related families regarding to the procedure.
- The clinician/nurse is equipped with full PPE (mask, gloves, and medical gown).
- Main vital signs of the patient are checked and monitored: blood pressure, pulse rate, respiration rate, and body temperature.
- The patient is positioned on the bed.

Note: Make sure the injury/wound is thoroughly visible to facilitate the wound care treatment.

- If the burn injury is covered within clothing or gauze dressings, through the permission of the patient, the dressing is uncovered to make it clearly visible.

Note: If the gauze is difficult to remove, wet the gauze with 0.9% NaCl and leave it for 10-20 minutes. Subsequently, remove the gauze gently.

2. Wound Cleansing and Debridement

- The burn injury is cleansed through wound irrigation: the kidney dish is placed under the wound area to collect the irrigation solution, followed by rinsing the wound under running 0.9% NaCl solution.
- Wound debridement is performed as follows:
 - If there is a necrotic tissue: the necrotic tissue is grasped with surgical tweezers and then cut using surgical scissors, starting from the thinner to the thicker part.
 - If there is a burn blister (bullae): the liquid is completely drained using a 10cc syringe from the lower part of the bullae. The affected skin is allowed to remain on its original position to cover the skin.
- Any liquid/moisture is removed by gently tapping the sterile gauze using tweezers against the wound area until it becomes completely dry.
- The secretome is dressed on the wound by applying 1 drop of secretome gel per 1 cm² wound area:
 - 1st – 2nd degree burn: 10% secretome gel
 - 3rd degree burn: 20% secretome gel
- The secretome is applied evenly using a sterile cotton bud and then allowed to sit for 5-10 minutes.

- Sofra-Tulle is fixed to cover the wound area.

Note:

- *If the wound is minor and small-sized, Tegaderm could be applied instead and changed 2 days after secretome application.*
- *If the wound is mild and dry, the wound dressing could be changed 2 days after secretome application.*
- *If the wound is wet, the wound dressing should be changed once a day after secretome application.*
- *Systemic therapy might be considered according to the patient's condition.*

- Sterile gauze is applied to the wound area.

2. Post-treatment Care

- The medical devices are disinfected and sterilized.
- The medical waste is collected and processed according to the standard procedure (*See SOP for Biological and Sharps Disposal*).
- The patient's general conditions are observed:
 - Blood pressure, pulse rate, respiration rate, and body temperature
- Progress of the patients is observed to determine whether or not the patient needs to be referred for outpatient/inpatient.