

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

Nama : **Dr. dr. Sukmawati Tansil Tan, Sp.KK dan Dr. dr. Siufui Hendrawan, M.Biomed**

Alamat : Union Square No.9, Gading Serpong, Tangerang, BANTEN, 15810

Kewarganegaraan : Indonesia

## Pemegang Hak Cipta

Nama : **Dr. dr. Sukmawati Tansil Tan, Sp.KK dan Dr. dr. Siufui Hendrawan, M.Biomed**

Alamat : Union Square No.9, Gading Serpong, Tangerang, BANTEN, 15810

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.

Surat Pencatatan Hak Cipta atau produk Hak terkait ini sesuai dengan Pasal 72 Undang-Undang Nomor 28 Tahun 2014 tentang Hak Cipta.



a.n Menteri Hukum dan Hak Asasi Manusia  
Direktur Jenderal Kekayaan Intelektual  
u.b.  
Direktur Hak Cipta dan Desain Industri

Anggoro Dasananto  
NIP.196412081991031002

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Dalam hal pemohon memberikan keterangan tidak sesuai dengan surat pernyataan, Menteri berwenang untuk mencabut surat pencatatan permohonan.

	<b>STANDARD OPERATING PROCEDURE (SOP)</b>	Document Num.: SOP/LB/2020
		Release date: 16 March 2023
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	Treatment of Burn Injury using MSCs Secretome	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. ddH<sub>2</sub>O
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 cm<sup>2</sup> wound area:

- 1<sup>st</sup> – 2<sup>nd</sup> degree burn: 10% secretome gel
- 3<sup>rd</sup> 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.