

CERTIFICATE OF ANALYSIS

HUMAN SKIN TISSUE AND DERIVATED PRODUCTS

Catalog number: STR003

Batch number: STR003021-OC01

FOR IN VITRO AND RESEARCH USES ONLY

For your safety /// Biohazard information /// These biologicals have to be considered as potentially dangerous, take maximum care in order to protect yourself, your colleagues and your environment.

According to French laws, this product is considered as “product and element of body taken during a surgical procedure”, and used for scientific research, French law L.1245 CSP.

1 BIOLOGICAL MATERIAL

INFORMATION		Comments		
<ul style="list-style-type: none"> • Sex • Origin • Anatomical site • Age • BMI 	<ul style="list-style-type: none"> • female <input checked="" type="checkbox"/> male <input type="checkbox"/> • Caucasian <input checked="" type="checkbox"/> African <input type="checkbox"/> Other <input type="checkbox"/> • abdomen <input type="checkbox"/> breast <input checked="" type="checkbox"/> face <input type="checkbox"/> other <input type="checkbox"/> • 59 years old • Not available 			
SAFETY DATA				
Virological status	Specification	Result		
<ul style="list-style-type: none"> • Hepatitis B (<i>HBs antigen, anti HBc antibody</i>) • Hepatitis C (<i>anti HCV antibody</i>) • HIV-1 and HIV-2 (<i>anti HIV-1 and -2 antibodies</i>) 	Negative	Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> In progress <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> In progress <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> In progress <input type="checkbox"/>		
<i>Virological status for HIV1-2, HCV, HBV is carried out on the patient by serological screening using approved diagnostic kits.</i>				
Biosafety level	All human sourced products should be handled at the Biological Safety Level. 2 (BSL 2) to minimize exposure of potentially infectious products			
DESCRIPTION				
Skin decontamination before surgery		Comments		
Betadine	<input type="checkbox"/>	Hibitane	<input type="checkbox"/>	
Betadine alcohol	<input type="checkbox"/>	Hibiscrub	<input type="checkbox"/>	
Betadine scrub	<input type="checkbox"/>	Chlorhexidine	<input type="checkbox"/>	
Chlorhexidine alcohol	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>	



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Shipping conditions between the sampling site and Biopredic		Comments
Time		
<ul style="list-style-type: none"> • Transit time less than 6 h • Transit time less than 12 h 	<input checked="" type="checkbox"/> <input type="checkbox"/>	Real time: 3H00
Temperature		
<ul style="list-style-type: none"> • Room temperature • Between +4°C and +15°C • At less than -20°C 	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	

2 PRODUCT

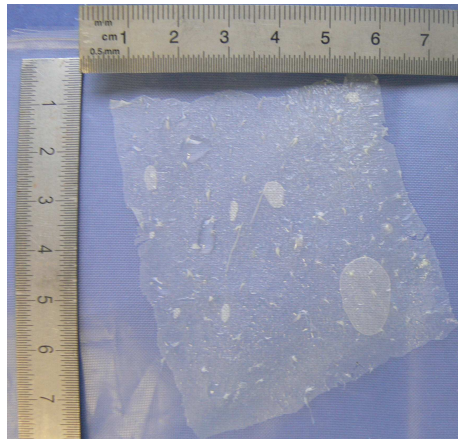
Production information							
<ul style="list-style-type: none"> • Surgery date • Production date • Production performed on 		November 07, 2011 at 3h00 PM November 08, 2011 at 00h50 PM fresh skin <input checked="" type="checkbox"/> frozen skin <input type="checkbox"/>					
<ul style="list-style-type: none"> • Full thickness skin with adipose tissue • Full thickness skin without adipose tissue • Dermatomed skin • Stratum corneum 		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>					
Fresh	<input type="checkbox"/>	Frozen	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>	/	
Surface	35 cm ²						

3 CONTROL

Macroscopic examination of the full-thickness skin					
• Presence of stretch marks	Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>	
• Presence of scars	Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>	
• Presence of marks (surgical marker)	Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>	
• Presence of pubic hair	Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>	

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Skin picture



4 STORAGE AND DELIVERY

Storage	
<ul style="list-style-type: none"> • At room temperature • At 4°C • At - 20°C • At - 80°C 	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Delivery	
<ul style="list-style-type: none"> • At room temperature • At 4°C • At lower than - 20°C 	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>

VISA FOR BATCH RELEASE

Name	Signature	Date
Nathalie ROUGIER, PhD		November 15, 2011